Supreme Court, U.S.
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No.

In The

Supreme Court of the United States

October Term, 1998

BRIAN KEITH STUART, a minor, by his natural Guardian and next friend Pamela Jean Craven; PAMELA JEAN CRAVEN, individually; PAULA KAIRDOLF; ERROLL M. KAIRDOLF, as parents and natural guardians of Michella Renee Kairdolf, a minor; PAULA KAIRDOLF, individually; ERROLL M. KAIRDOLF, individually, on behalf of themselves and all others similarly situated,

Petitioners,

- v. -

AMERICAN CYANAMID COMPANY, a wholly owned subsidiary of American Home Products Corporation,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Where paralyzed victims of Orimune oral polio vaccine allege fraud and fraudulent concealment by the vaccine's manufacturer and all fraud and fraudulent concealment alleged by plaintiffs has been admitted by the vaccine manufacturer, does the grant of summary judgment in favor of the manufacturer violate this Court's holdings in *Celotex v. Catrett* and *Anderson v. Liberty Lobby* where district court judge makes the following finding: "[P]laintiffs have failed to provide evidence of any affirmative act of fraudulent concealment by Cyanamid. The only evidence of wrongdoing offered by the plaintiffs concerns the government's improper approval of Orimune, not fraud by Cyanamid. As a consequence, the doctrine of equitable tolling can not be effectively invoked by the plaintiffs to avoid the statute of repose."?

2. Can American Cyanamid, which plaintiffs allege secured its production license by making fraudulent representations to the regulatory agency, the Division of Biologic Standards, that it had fully tested its master seeds and its production seeds and the pools of vaccine derived therefrom and continued to explicitly warrant regulatory compliance, use as its defense to personal injury actions that the paralyzed victims of the product Orimune should have discovered its non-compliance even when the fraud and the fraudulent concealment were stipulated to, and when fraud and fraudulent concealment continues in the instant action notwithstanding the statutory requirements of the Public Health Act, 42 U.S.C. § 262 (1991 & Supp. 1998), and the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq. (1972 & Supp. 1998)), as interpreted by this Court in *Berkovitz v. United States*, 486 U.S. 531 (1988)?

3. Do the federal statutes and regulations governing the production of oral polio vaccine, as articulated by the Supreme Court in *Berkovitz v. United States*, apply only to the licensing agency, as defendant American Cyanamid has claimed, so that the vaccine manufacturer's violations of its licensing responsbilities are inconsequential and confer no recourse upon the paralyzed victims of its improperly licensed product?

4. Where the manufacturer of Orimune polio vaccine furnishes an affidavit as part of its Motion for Summary Judgment swearing that the regulatory agency approved each and every "seed" and each and every "lot" of its Orimune vaccine, when it knew such an affidavit to be false, does this, in and of itself, preclude the court from making a finding of fact that the plaintiffs should have discovered the fraud when the vaccine manufacturer continues with the fraud in the litigation in which the motion is brought?

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
TABLE OF CONTENTS TO THE APPENDIX	viii
OPINIONS BELOW	1
JURISDICTION	1
STATUTES INVOLVED IN THE CASE ...	2
STATEMENT OF THE CASE	2
Background.....	8
Proceedings Below	10
REASONS FOR GRANTING THE WRIT.	11
I. The Writ Should Be Granted to Cure The Court of Appeals' Failure To Properly Apply This Court's Holdings in *Celotex* And *Anderson* To Defendant's Rule 56 Motion......	11

II. The Petition Should Be Granted To Allow Plaintiffs To Prove That The Vaccine Manufacturer Fraudulently Warranted Compliance With the Federal Oral Poliovirus Vaccine Safety Standards When There Has Been No Such Compliance. 13

CONCLUSION. 19

APPENDIX . . . . . A.1 *et seq.*

TABLE OF AUTHORITIES

CASES

	Page
Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986).	11
Baker v. United States, 817 F.2d 560 (9th Cir. 1987)	14
Berkovitz v. United States, 486 U.S. 531 (1988)	2, 12, 13, 14, 16, 18
Boyd v. Louisiana Medical Mutual Insurance Company, 593 So. 2d 427 (La. App. 1991) . . .	8, 18
Celotex Corp. v. Catrett, 477 U.S. 317 (1986)	11, 15
Dunn v. Lederle Laboratories, 121 Mich. App. 73, 328 N.W.2d 576 (1982)	8, 17
Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977)	8

Page

In Re Sabin Oral Polio Vaccine Products Liability Litigation, 743 F. Supp. 410 (D. Md. 1990), 763 F. Supp. 811 (D. Md. 1991), 763 F. Supp. 952 (D. Md. 1991), *aff'd*, 984 F.2d 124 (4th Cir. 1993) 12

Johnson v. American Cyanamid Company, 718 P.2d 1318 (Kan. 1986), *aff'd*, 758 P.2d 206 (Kan. 1988)..... 8, 17

Kearl v. American Cyanamid, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (Ct. App. 1985) 8,17

Loge v. United States, 662 F.2d 1268 (8th Cir.1981), *cert. denied*, 456 U.S. 944 (1982) 14

Plummer v. Lederle Laboratories, 819 F.2d 349 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987) .. 8,17

Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1976)..... 8

Schindler v. Lederle Laboratories, 725 F.2d 1036 (6th Cir. 1983)..... 8

Sheehan v. Pima County, 660 P.2d 486 (Ariz. App. 1982)..... 8, 17, 18

Page

Snawder v. Cohen, 749 F. Supp. 1473,
804 F. Supp. 910 (W.D. Ky. 1992),
aff'd, 5 F.3d 1012 (6th Cir. 1993) 8

Stuart v. American Cyanamid Company,
1997 WL 695578, *aff'd*,
158 F.3d 622 (2d Cir. (N.Y.)
Sep. 21, 1998)(No. 97-9548) 1, 10

United States v. Dotterweich,
320 U.S. 277 (1943) 16

United States v. Sullivan,
332 U.S. 689 (1948) 16

STATUTES

Food Drug and Cosmetic Act (FDCA),
21 U.S.C. §§ 301 *et seq.*
(1972 & Supp. 1998) 2

28 U.S.C. § 1254(1) 1

Public Health Act, 42 U.S.C. § 262
(1991 & Supp. 1998) 1, 2

National Childhood Vaccine Injury
Compensation Act,
42 U.S.C. §§ 300aa *et seq.* 17

Page

42 U.S.C. § 300aa-23 (A.9) 17

21 C.F.R. Part 630 2

42 C.F.R. Part 73 2

42 C.F.R. § 73.114(b)(1)(iii) (1991) 12

Fed. R. Civ. P. 56 . . . . . 11, 13

TABLE OF CONTENTS
TO THE APPENDIX
TO THE PETITION

Opinion of the United States Court of Appeals for the Second Circuit, reported at 158 F.3d 622 (2d Cir. 1998) A.1

Opinion of the United States District Court for the Southern District of New York, reported at 1997WL695578. . . . A.2

Order of the United States Court of Appeals for the Second Circuit, denying Appellants' Petition for Rehearing or Rehearing En Banc A.3

42 U.S.C. § 262 . . . . . A.4

Affidavit of Dr. David McClintock in support of American Cyanamid Company's motion for summary judgment, dated February 5, 1996 ..... A.5

Excerpts from American Cyanamid's statement pursuant to Southern District of New York Local Rule 3(g) (statement of material facts as to which there is no genuine issue) A.6

Letter from American Cyanamid counsel Daniel J. Thomasch, Esq. to plaintiffs' counsel Marc S. Moller, Esq., dated January 19, 1996 ..... A.7

Excerpts of the allegations in plaintiffs' complaint filed in the Southern District of New York A.8

42 U.S.C. § 300aa-23 ..... A.9

PETITION FOR A WRIT OF CERTIORARI

Minor Brian Stuart and his mother Pamela Craven, and minor Michella Kairdolf and her parents Paula and Errol Kairdolf, respectfully seek a Writ of Certiorari to review the decision of the United States Court of Appeals for the Second Circuit, which affirmed a Summary Judgment Order issued by the United States District Court for the Southern District of New York on September 21, 1998 and denied petitions for rehearing and rehearing *en banc* on November 6, 1998.

OPINIONS BELOW

The opinion of the Court of Appeals (A.1)[1] is reported at 158 F.3d 622 (2d Cir. (N.Y.) Sep. 21, 1998)(No. 97-9548). The order of the District Court appealed from (A.2) is reported at 1997 WL 695578. The Order of the Court of Appeals denying plaintiffs' petition for rehearing or rehearing *en banc* (A.3) is unpublished.

JURISDICTION

The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

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[1] References to the Appendix which is bound in this volume are preceded with the designation "A.___".

STATUTES INVOLVED IN THE CASE

The Public Health Act, 42 U.S.C. § 262 (1991 & Supp. 1998) (A.4), and the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* (1972 & Supp. 1998)) were enacted by Congress to afford members of the public the greatest possible protection in the medical use of drugs and vaccines and to impose on manufacturers of drugs and vaccines a standard of care requiring strict adherence to promulgated regulations and the licenses which are awarded to a successful applicant. Only when such a license is issued may an entity manufacture, distribute or sell a new drug or vaccine. Regulations specific to polio vaccine's licensing and manufacture were promulgated at 42 C.F.R. Part 73 and renumbered as 21 C.F.R. Part 630. This Court in *Berkovitz v. United States*, 486 U.S. 531 (1988), held that vaccine regulations for licensure required submission of data, performance of tests, and a review to determine full compliance.

STATEMENT OF THE CASE

This Court held in *Berkovitz v. United States*, 486 U.S. 531, 541-542 (1988), that in order to receive a license for Orimune, a manufacturer had to demonstrate and supply to the regulatory agency all the necessary data and test results as part of its license application. This Court enumerated the requirements necessary and ruled that an OPV license can be issued only after the submission of the required data and a determination that the data and test results fulfill the regulatory requirements. *Berkovitz*, *supra*, at 541. The license *cannot be considered as filed* until all the data and tests have been submitted. *Berkovitz*, *supra*, 541, 542.

In the license application for Orimune, the manufacturer warranted to the United States that it had performed all the tests and that it had fully complied with the statutory requirements. On every label of Orimune, on every package insert, and in every Physicians' Desk Reference from 1962 to 1990, Lederle published the following statement in regard to Orimune:

> * * * The manufacturer makes no representation or warranty, expressed or implied, with respect to the merchantability or fitness for use of this vaccine other than that the vaccine has been produced in accordance with the standards for its production prescribed by the United States Food and Drug Administration and applicable thereto at the time of its release by the manufacturer.

In an affidavit filed on behalf of American Cyanamid by its Senior Director and Responsible Head of regulatory affairs and technical assessment in the instant litigation,[2] American Cyanamid swore to the Court on February 5, 1996:

> Every seed that Cyanamid has used in the manufacture of Orimune was first officially

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[2] The regulations define the Responsible Head as follows: "A person shall be designated as the responsible head who shall exercise control of the establishment in all matters relating to compliance with the provisions of this subchapter, with authority to represent the manufacturer in all pertinent matters with the Bureau of Biologics, and with authority to enforce or to direct the enforcement of discipline and the performance of assigned functions by employees engaged in the manufacture of products.

> approved for use, as compliant with applicable federal regulations, by the appropriate federal administrative agency, which at all times was either the DBS or a division of the Food and Drug Administration ("FDA").

A.5 ¶ 5., A-199.[3] In the same affidavit it further swore:

> Prior to distributing any particular lot of OPV to the medical community, Cyanamid was required by federal regulations to test the lot in the manner directed by the applicable federal regulations and to submit the test result data and samples of the lot to the DBS or FDA for analysis. . . . Cyanamid has received such a DBS or FDA release each and every lot of Orimune that it has distributed and would not under any circumstances distribute a lot without receiving such a DBS or FDA release.

In an exchange between a justice of this Court and the Deputy Solicitor General, the following exchange occurred during *Berkovitz*:

> "QUESTION: [Supposing the DBS] did not make any examination of the application at all, or any determination other than some papers have been filed and I will now issue the license. "Would that comply with the regulation? "[COUNSEL]: No, it would not comply with the regulation. "QUESTION: It would violate a

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[3] Citations to documents as numbered in the Joint Appendix before the Second Circuit are designated "A-[]".

> mandatory duty ..., wouldn't it? "[COUNSEL]: In the extreme instance you are talking about . . . , it would definitely violate that regulation." Tr. of Oral Arg. 34-35.

Berkovitz, supra, at 544 n.10.

In the instant case, American Cyanamid conceded all the allegations of fact alleging the fraud and fraudulent concealment pursuant to its request before the District Court to bring a summary judgment motion.[4] Accordingly, the trial judge precluded plaintiffs from taking discovery. In its brief to the trial court, notwithstanding its stipulation, American Cyanamid constantly relied upon the McClintock affidavit to defeat plaintiffs' fraud and fraudulent concealment argument. "In addition to granting Cyanamid a Product License for the production of Orimune, the DBS, and later the FDA, has also approved and 'released' every lot of Orimune that Cyanamid has ever distributed." McClintock Aff. para. 6, Ex. C, as quoted in Defendant's Brief in Support Of Summary Judgment at 10.

* * *

> Regardless of which seed Cyanamid has used, Cyanamid has never distributed a lot of Orimune that had not first been 'released' by the DBS or the FDA.

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[4] Although the document in which Cyanamid counsel memorialized this concession was not included as part of the appeal appendix, the letter, dated January 19, 1996, was entered into the record at oral argument before the Second Circuit. It appears at A.7.

Id. at 10, 11.

> Indeed, the DBS licensed Cyanamid's OPV program and the DBS ad FDA specifically approved every single lot of Orimune that Cyanamid has distributed including those administered to plaintiffs. (McClintock Aff. para. 6.)

Id. at 18.

During the appellate briefing, once again American Cyanamid referenced the Affidavit in defense of its position that there had been no fraud or fraudulent concealment:

> In addition to granting Cyanamid a product license for the production of Orimune, the DBS, and later the FDA, has also approved and 'released' every lot of Orimune that Cyanamid has ever distributed. (A-222; A-191-95).

Appellee's Answering Brief at 14.

> Cyanamid has never distributed a lot of Orimune that had not first been 'released' or licensed by the DBS or the FDA. (A-200).

Id.

> Plaintiffs do not, and could not, claim that Cyanamid failed to disclose accurately and completely its test results on lots of Orimune that were released by the government.

Id. at 15.

> Plaintiffs' failure to convince the court below of its 'fraudulent concealment' tolling argument is not attributable to Judge Cote's rejection of pleaded facts, but rather to the district court's proper appraisal of the significance of the facts that Cyanamid allegedly concealed to the issue of timeliness.

Id. at 4.

When counsel for Appellant raised the issue in the Court of Appeals about the fraudulent concealment, Appellee dismissed that argument with a footnote:

> Plaintiffs' argument that Cyanamid continues to commit "fraudulent concealment" by denying liability and refusing to admit that its lots of Orimune violated federal regulations, . . . if accepted, would eviscerate statutes of limitation in product liability cases, as no claim would ever be time-barred so long as a defendant continues to contest liability.

Brief of Defendant-Appellee American Cyanamid Company at 39 n.11.

In its statement of uncontested facts, in paragraphs 6 through 27 (A.6), defendant American Cyanamid claimed to have complied with every regulation from licensing through the release of the individual vaccine lots based upon the affidavit it submitted. At the same time, it admitted all the facts disputing these statements as contained in the plaintiffs' complaint. *See*, as to licensing, plaintiffs' complaint, ¶¶ 35 through 40; as to the

testing of the seeds, ¶¶ 41 through 76; as to the testing of each and every vaccine lot, *see* ¶¶ 77 through 91.[5]

Notwithstanding the trial court's finding that there was no affirmative evidence of fraud produced by plaintiffs, ¶¶ 112 - 127 of the complaint (A.8) were admitted to by defendant for all purposes under Fed. R. Civ. P. 56.

Background

Brian Stuart has been a triplegic since receiving a dose of Orimune on March 19, 1979 in Nebraska. In order for Brian to receive the vaccination, his mother signed a form prepared by the Centers for Disease Control which warned of some danger associated with the use of oral poliomyelitis vaccine. Counsel was retained in 1979 and has remained counsel until today. That counsel initially advised Mrs. Craven that she "had a case." After further research, it was determined that *there was no viable claim* because American Cyanamid had complied with the holdings in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. den.*, 419 U.S. 1096 (1976), and *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977). Every Court in the United States presented with this issue has ruled that the warning in the CDC forms or in the package inserts or the Physicians' Desk Reference was adequate as a matter of law after 1973.[6]

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[5] The referenced portions of plaintiffs' complaint are annexed as A.8.

[6] *See, e.g., Johnson v. American Cyanamid Company*, 718 P.2d 1318 (Kan. 1986), *aff'd*, 758 P.2d 206 (Kan. 1988); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2d Cir.), *cert.*

Michella Renee Kairdolf was paralyzed in 1983 in Louisiana. Neither she nor her family received any warning.

The trial court found that as to Brian Stuart, Nebraska's statute of repose expired on March 19, 1989, and as to Michella Renee Kairdolf, Louisiana's statute of limitations expired on March 17, 1988.

Though neither parent of the minor plaintiffs knew their children had been evaluated by the Centers for Disease Control, defendant American Cyanamid was fully aware that they were evaluated, knew which of its vaccine pools were involved with the paralysis, and was aware both children were determined to be cases of recipient vaccine-associated polio, with Type isolated. As a result of this notice to defendant years in advance of the claims which Cyanamid now contends are stale, the entire concept behind the statute of limitations and statute of repose -- relieving a defendant of the need to defend against stale claims for which documentation and witnesses may be sparse or absent -- is not applicable to the fact situation. The records American Cyanamid would have had to maintain to defend the instant claims and other similar claims are still in its possession, as the applicable statute of limitations has not expired for injured minors in most of the states of this nation.

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denied, 484 U.S. 898 (1987); *Kearl v. American Cyanamid*, 172 Cal.App.3d 812, 218 Cal Rptr. 453 (Ct. App. 1985); *Schindler v. Lederle Laboratories*, 725 F. 2d 1036 (6th Cir. 1983); *Dunn v. Lederle Laboratories*, 121 Mich.App. 73, 80, 328 N.W.2d 576, 580 (1982); *Sheehan v. Pima County*, 660 P.2d 486 (Ariz. App. 1982); *Snawder v. Cohen*, 749 F. Supp. 1473, 804 F. Supp. 910 (W.D. Ky. 1992), *aff'd* 5 F.3d 1012 (6th Cir. 1993); *Boyd v. Louisiana Medical Mutual Insurance Company*, 593 So.2d 427 (La. App. 1991).

Proceedings Below

A class action was brought on behalf of Michella Kairdolf and her parents, Brian Stuart and his mother, and all others similarly situated who were paralyzed and who had suffered damages as a result of American Cyanamid's Orimune vaccine. The lawsuit was assigned to Judge Cedarbaum in the Southern District of New York on October 27, 1995. At the behest of the defendant, which requested permission to file a motion for summary judgment, plaintiffs withdrew their motion for class certification before Judge Cedarbaum.

The case was then transferred to Judge Leisure, who recused himself. The action was reassigned to Judge Allen G. Schwartz, and on January 22, 1996, plaintiffs were precluded from taking discovery by the court because American Cyanamid agreed to accept the factual allegations of the complaint as true for all purposes, *including all allegations of fraud and fraudulent concealment* (A.7).

After discovery, which was limited solely to the disclosure defendant requested, the parties filed their briefs. Cyanamid's first brief filed in the trial court was in February 1996 and included the affidavit of the Responsible Head of American Cyanamid which included the false statements heretofore quoted (A.5). Oral argument was set for the first week of April, 1996, which date was adjourned *sine die*.

Nothing further occurred until June 1997, when Judge Robert Sweet was re-assigned the case. Judge Sweet set November 5, 1997 for a status conference, but on that date, an opinion and order by Judge Denise Cote was entered by the Clerk. A.2. Judgment was not entered until February 11, 1998.

The Court of Appeals affirmed Judge Cote's Opinion. 158 F.3d 622 (2d Cir. (N.Y.) Sep. 21, 1998)(No. 97-9548). A.1. A subsequent Petition for Reargument and a Hearing *En Banc* was denied on November 6, 1998. (A.3.) The Order of the

Court of Appeals denying rehearing or rehearing *en banc* is not officially reported.

REASONS FOR GRANTING THE WRIT

I. The Writ Should Be Granted to Cure The Court of Appeals' Failure To Properly Apply This Court's Holdings in *Celotex* And *Anderson* To Defendant's Rule 56 Motion.

This Court should grant the Petition for Certiorari to correct the mis-application of this Court's pronouncements in *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-32 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986), concerning Fed. R. Civ. P. 56, especially where fraud and fraudulent concealment are at issue. Where there has been admission of fraud and fraudulent concealment, and, therefore, no discovery was permitted to the plaintiffs, the entire rationale behind the Federal Rules of Civil Procedure and this Court's interpretation of these rules will be vitiated if federal courts can disregard those factual admissions meant to govern the determination of Rule 56 motions and make contrary findings of fact based upon an affidavit which is contradictory to the admissions made. Those cases restrict the granting of Rule 56 motions to cases where there are no issues of fact. In the instant case, every issue is contested between the parties, including the issues of fraud and fraudulent concealment, which would toll statutes of repose and limitation in both plaintiffs' jurisdictions.

This Court has interpreted Federal Rules of Civil Procedure 56 to allow the granting of summary judgment only where there has been full discovery and no material issues of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-32 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In

the instant action, plaintiffs were permitted no discovery because the defendant conceded each and every fact alleged by plaintiffs in their complaint, including the violation of every regulation relating to licensing and approval of the Orimune product. A.7. American Cyanamid filed an affidavit claiming just the opposite (A.5) and repeatedly cited to that affidavit for the premise that there was no fraud or fraudulent concealment because there were no violations of the law.

The court's determination that plaintiffs failed to have affirmatively proven the fraudulent concealment could only have been the result of the numerous transfers between district judges, the lack of oral argument, and the trial court's lack of knowledge why Judge Schwartz had granted only limited discovery and had permitted only defendant to engage in discovery.

That the trial court did not fully understand the full ramifications of the documents and the concession of fraud can be seen by the court's mis-interpretation of the *In Re Sabin*[7] litigation and the importance of compliance with the neurovirulence test regimen:

> The Fourth Circuit also affirmed the district court's finding that DBS had violated 42 C.F.R. § 73.114(b)(1)(iii) (1991), by releasing vaccine lots that impermissibly exceeded the potency of the reference poliovirus approved by the National Institute of Health. In Re Sabin, 984 F.2d at 126-27.

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[7] *Berkovitz v. United States* is one of the cases in *In Re Sabin Oral Polio Vaccine Products Liability Litigation*, 743 F. Supp. 410 (D. Md. 1990), 763 F. Supp. 811 (D. Md. 1991), and774 F. Supp. 952 (D. Md. 1991), *aff'd*, 984 F.2d 124 (4th Cir. 1993).

A.2 at 5. Though potency was important, it was Cyanamid's failure to abide by the *neurovirulence* regulations which caused the paralysis of the minor plaintiffs herein and all other individuals similarly situated.

In light of the affirmative representation of compliance which Cyanamid made to the administering physicians to both infant plaintiffs, the material facts as to whether proper licensure had occurred goes to the heart of this matter, because this Court has already spoken as to the effect of improper licensure. *Berkovitz v. United States*, *supra* at 540-41.

If this case is remanded to the trial court, it will be a simple matter to determine which of the parties is telling the truth as to this dispute over regulatory compliance. If American Cyanamid is telling the truth, it will have all the test results, all the approvals, and the verification that the United States in fact approved every lot of vaccine. Dr. McClintock, the affiant of the affidavit relied upon to support the Rule 56 motion, would have to have seen these documents to have given his affidavit, since he states that his assertions are on personal knowledge and/or review of records kept in the ordinary course of business. If, on the other hand, the facts are as plaintiffs state (which were admitted to by defendant for purposes of its motion), then there will be no record showing submittal of all the data, the test results therefrom, and the approvals for use of each seed and each resulting vaccine lot.

II. The Petition Should Be Granted To Allow Plaintiffs To Prove That The Vaccine Manufacturer Fraudulently Warranted Compliance With the Federal Oral Poliovirus Vaccine Safety Standards When There Has Been No Such Compliance.

This Court should grant the Petition for Certiorari to declare unquestionably that the decision of *Berkovitz v. United States, supra*, and the Circuit decisions of *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982), are equally applicable to the vaccine manufacturer. The manufacturer which has not performed required tests and not submitted the required test data cannot be considered a licensed manufacturer. The manufacturer which fraudulently claims to have performed the licensing tests and submitted the licensing test data cannot escape its regulatory violations by continuing that fraud in subsequent litigation.

If the Petition for Certiorari is not granted, every litigant who desires to move for summary judgment where there are factual disputes will in one breath admit to the facts (*i.e.*, the fraud and fraudulent concealment) and in another file an affidavit stating there was no fraud, and then claim, as here, that plaintiff should have discovered the fraud in any event.

If the Petition for Certiorari is not granted, every decision of every Circuit Court of Appeals which has required a vaccine manufacturer to comply with federal regulatory requirements for licensing and manufacture of polio vaccine will be *de facto* overruled. Under the Second Circuit's decision, to escape liability, a vaccine/drug manufacturer need do no more than claim compliance, not comply with the regulations, and then claim that its victims should have discovered their fraud before any limitations or repose period elapsed.

If the Petition for Certiorari is not granted, American vaccine manufacturers, which have the duty to insure the safety, purity and potency of their product, 42 U.S.C. § 262(d), will only pay lip service to the mandatory statutory and regulatory requirements and will totally disregard its obligation under the law as interpreted by this Court in *Berkovitz v. United States, supra*, knowing that no liability will result from permitting

vaccine to be sold in violation of the Food, Drug and Cosmetics Act or the Public Health Act.

If the Petition for Certiorari is not granted, every American who in the future suffers any adverse reaction which is noted in a drug's package insert, in the Physicians Desk Reference, or in a consent form, will necessarily have to commence a civil action to protect against the off-chance that the drug manufacturer/vaccine manufacturer may have defrauded the government, physicians, the courts, or the ultimate consumer-patient in order to avoid the imposition of the statute of repose and/or statute of limitations raised by the non-compliant vaccine manufacturer to effectively bar a valid cause of action.

Commencing litigation without a sound basis for a claim, especially where fraud is not appreciated, simply to defeat a potential prospective statute of limitations defense would flood courts with protective actions. That is not desirable and could only heavily burden already burdened federal court dockets. Yet, that is the implicit message of the Second Circuit's opinion herein and surely its lesson. Such a result would "surely defy common sense" as much as would the outcome Justice Rhenquist discussed in *Celotex, supra* at 326, when he posited the anomaly of Rule 56 being interpreted to confer power on a court to grant summary judgment *sua sponte*, but not if a party moved for such relief.

In examining the law which governs the conduct of a vaccine/drug manufacturer, the Supreme Court has already instructed the federal courts why the highest degree of care is required to adequately protect the drug/vaccine consumer:

> By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of

> people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

United States v. Dotterweich, 320 U.S. 277, 280 (1943); and *see generally United States v. Sullivan*, 332 U.S. 689, 698-703 (1948).

In the Petition asking this Court to accept jurisdiction in *Berkovitz*, the United States conceded that the question presented in that case was of paramount importance and that its resolution would have far-reaching consequences for the future regulatory supervision of vaccine and drug manufacturers. How much more so does the current litigation pose questions of the greatest importance as to the societal duties of a vaccine manufacturer whose product has been the sole cause of polio paralysis in the United States since 1979.

After this Court ruled in *Berkovitz* that a failure to follow *any* of the regulatory requirements as to OPV licensure would result in a dereliction of a mandatory duty on the part of the regulators, certainly the vaccine manufacturer to which the federal regulations are directed should not be allowed to escape liability by merely claiming that it met all regulatory requirements and filing an affidavit so stating, knowing that such records do not exist, specifically conceding that fraud and fraudulent concealment on a motion under Fed. R. Civ. P. 56, and then having a district court find that the tolling of statutes of limitation and repose which results from exactly such fraud does not apply because the fraud has not been demonstrated.

If the Court does not grant the Petition, American Cyanamid and other vaccine manufacturers will assume that the *Berkovitz* decision has no actual effect on their actions. They will assume that so long as they receive a license, whether it be

a nullity or not will not matter because they can always contend that the mere existence of the license constitutes evidence of compliance.

During all times relevant herein, a vaccine manufacturer was subject to the Public Health Act, 42 U.S.C. 262; the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* (1972 & Supp. 1998), the general and specific regulations enacted under both statutes, and the interpretations of this Court. American Cyanamid and other vaccine makers requested protection from lawsuits, claiming they had complied fully with these acts but were nevertheless being sued for the failure to warn. That led to the enactment of the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa *et seq.*. When Congress enacted that legislation, it provided only two exceptions for the institution of lawsuits: where there has been a falsification of data in the licensing of the product or a falsification with respect to safety or efficacy of the individual vaccine lots released. 42 U.S.C. § 300aa-23 (A.9). Clearly, Congress did not envision that the manufacturer of the polio vaccine had been guilty of *both* these violations. On what basis can injured minor plaintiffs know more than this country's legislators about a federally regulated entity?

In 1988 and 1989, when the two minor plaintiffs should have instituted a lawsuit according to the trial court and the Second Circuit, there was no good faith basis for a suit. As to Brian, his mother was given a warning. *See Kearl v. American Cyanamid, supra; Sheehan v. Pima County, supra.* As to Michella, although she was not given a warning, every court considering other polio vaccine cases determined that since the learned intermediary rule was applicable, her physician was "given a warning," and that was sufficient. *See Plummer v. Lederle Laboratories, Johnson v. American Cyanamid, Dunn v. Lederle Laboratories*, n.6 of this Petition, *supra.*

Even as to the physician who did not extend the warning to his patient, the courts have determined that it would be

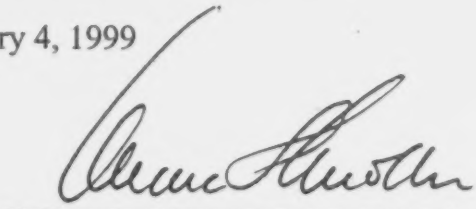
unreasonable for a parent *not* to have vaccinated a child where the risk was so "*de minimis*." *See Boyd, supra, Sheehan, supra*. Those courts had been misled in finding Orimune unavoidably unsafe because they accepted unquestioningly the warranty contained in the Orimune package insert, the affidavits filed on behalf of American Cyanamid similar to that of Dr. McClintock submitted herein, and the sworn testimony of witnesses in each of those cases that American Cyanamid had complied, and each of the three types of its polio vaccine was properly licensed. If no court nor any other litigant had discovered the fraud and fraudulent concealment, on what basis did the court below find that the minor plaintiffs could have discovered the ongoing fraud, failing which, their claims would be dismissed?

In this instance, the fraud started in 1962 with the license application, when American Cyanamid claimed to have performed the tests, but never furnished the data. It did not furnish the data because it had not, in fact, performed all the tests. The precise question which this Court asked the deputy Solicitor General in *Berkovitz* is no longer a hypothetical; it is reality. The "extreme situation" envisioned by this Court (*Berkovitz*, *supra*, at 544 n.10.) in fact occurred. Neither American Cyanamid nor the United States wants that fact to become public knowledge. That is why the fraud has continued until today. Cyanamid has continued to operate, knowing that its licensing data were never submitted and that the license it was issued was a nullity. As this Court has stated, unless the data are filed, no license can be issued.

CONCLUSION

The Petition for Certiorari should be granted to correct both a fraud on the court and the fraud and fraudulent concealment which American Cyanamid commenced in 1962 and continues until today. For all the reasons stated herein, the Petition for Writ of Certiorari should be granted.

DATED: February 4, 1999



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APPENDIX

TABLE OF CONTENTS
TO THE APPENDIX
TO THE PETITION

Opinion of the United States Court of Appeals for the Second Circuit, reported at 158 F.3d 622 (2d Cir. 1998) A.1

Opinion of the United States District Court for the Southern District of New York, reported at 1997WL695578. . . . A.2

Order of the United States Court of Appeals for the Second Circuit, denying Appellants' Petition for Rehearing or Rehearing En Banc A.3

42 U.S.C. § 262 . . . . . A.4

Affidavit of Dr. David McClintock in support of American Cyanamid Company's motion for summary judgment, dated February 5, 1996 . . . . . A.5

Excerpts from American Cyanamid's statement pursuant to Southern District of New York Local Rule 3(g) (statement of material facts as to which there is no genuine issue) A.6

Letter from American Cyanamid counsel Daniel J. Thomasch, Esq. to plaintiffs' counsel Marc S. Moller, Esq., dated January 19, 1996 ..... A.7

Excerpts of the allegations in plaintiffs' complaint filed in the Southern District of New York A.8

42 U.S.C. § 300aa-23 ..... A.9

OPINION OF THE SECOND CIRCUIT BELOW
158 F.3D 622 (2d. Cir. 1998)

Brian Keith STUART, a minor, by his natural guardian and next friend Pamela Jean Craven; Pamela Jean Craven, individually; Paula Kairdolf; Errol M. Kairdolf, as parents and natural guardians of Michella Renee Kairdolf, a minor; Paula Kairdolf, individually; Errol M. Kairdolf, individually, on behalf of themselves and all others similarly situated, Plaintiffs-Appellants,

v.

AMERICAN CYANAMID COMPANY, a wholly owned subsidiary of American Home Products Corporation, Defendant-Appellee. American Home Products Corporation, Defendant.

No. 97-9548.

United States Court of Appeals,
Second Circuit.

Argued June 17, 1998.

Decided Sept. 21, 1998.

Before: MINER, McLAUGHLIN, and LEVAL, Circuit Judges.

BACKGROUND

McLAUGHLIN, Circuit J.

Polio is a disease of the central nervous system for which Dr. Jonas Salk developed a vaccine in 1955. The Salk vaccine was an

inactivated polio vaccine ("IPV"), derived from a dead polio virus. Although the Salk vaccine dramatically decreased the incidence of polio, it did not eradicate the disease.

While Dr. Salk was developing his IPV which had to be injected, other scientists, notably Dr. Albert Sabin, were working on an oral polio vaccine ("OPV"). Unlike IPV, OPV is produced from a live virus that is attenuated, but not killed, during the production process. OPV has several advantages over Dr. Salk's IPV. First, OPV is less expensive and requires only a single dose, as opposed to three inoculations of IPV and a follow-up booster shot. In addition, a person who receives OPV cannot transmit polio. In contrast, persons inoculated with IPV can serve as carriers of the disease, even though they would not themselves be infected.

OPV, however, is no more a miracle drug than an IPV injection. Like all vaccines cultivated from live viruses, OPV creates immunity by inducing a mild infection in the recipient. Thus, a person who receives OPV, or comes in close contact with such a recipient during the infection period, may develop polio.

In 1960, the Surgeon General of the United States approved OPV for use in the United States. One year later, the Division of Biological Standards of the National Institutes of Health ("DBS"), adopted regulations governing the issuance of manufacturing licenses for OPV. In 1962, American Cyanamid Company ("Cyanamid"), which had purchased the vaccine material developed by Dr. Sabin, applied to the DBS for a license to manufacture OPV. The DBS licensed Cyanamid to manufacture and sell OPV. Since 1963, Cyanamid has distributed an OPV product under the trade name "Orimune."

A. The Craven/Stuart Action

On December 9, 1978, Brian Stuart was born in Nebraska. At the age of three months, Brian received Orimune at the University of Nebraska Medical Center Clinic. Within thirty days of receiving the vaccine, he became permanently paralyzed. In May 1979, doctors told Brian's mother, Pamela Jean Craven, that they were "99 percent certain" that Brian's paralytic condition was caused by a

vaccine-induced polio infection.

Later that month, Craven retained an attorney, Daniel Cullan, to pursue Brian's legal rights with respect to the vaccine-induced polio. Attorney Cullan informed Ms. Craven that she "had a case." However, no suit was commenced against Cyanamid.

Eleven years later, Ms. Craven retained a new attorney, Edward Jelinek. On September 27, 1990, Attorney Jelinek and Ms. Craven filed a petition on Brian's behalf in the United States Court of Claims under the National Childhood Vaccine Injury Compensation Act of 1986 ("VCA"), 42 U.S.C. § 300aa et seq.. The VCA was established to compensate for specified injuries, including polio, caused by a covered vaccine.

In 1994, Craven changed counsel again, this time retaining Marc Moller and Stanley Kops. Acting on the advice of Moller and Kops, Craven withdrew the VCA petition on November 25, 1994, leaving no action pending on behalf of Brian Stuart.

B. The Kairdolf Action

Michella Kairdolf was born in Louisiana on November 22, 1982. Two months later, she received Orimune at the office of her pediatrician, ***626** Dr. James Michalik. Within thirty days, Michella became paralyzed. In August 1984, she was referred to the Centers for Disease Control of the United States Public Health Service and diagnosed as having vaccine-induced polio. Dr. James Bennett confirmed this diagnosis and informed Michella's parents, Errol and Paula Kairdolf, on March 17, 1987 that there was a "connection between the medical treatment [i.e., OPV vaccination] and [Michella's] disease."

The Kairdolfs filed a petition on behalf of Michella under the VCA on January 31, 1991. On October 24, 1994, acting on the advice of Moller and Kops, the Kairdolfs withdrew the petition, leaving no action pending on behalf of Michella.

C. The District Court Proceedings

On June 29, 1995, Pamela Craven, Paula Kairdolf, and Errol Kairdolf commenced a putative class action in the United States

District Court for the Southern District of New York against Cyanamid and its parent corporation, American Home Products. The action, brought on behalf of Craven, the Kairdolfs, Brian and Michella, and all other similarly situated persons alleged six theories of liability: (1) strict liability; (2) fraud; (3) negligence; (4) breach of implied warranty of merchantability; (5) breach of implied warranty of fitness for a particular purpose; and (6) breach of express warranty of fitness for a particular purpose.

The case was initially assigned to Judge Miriam Cedarbaum, who held a pretrial conference. Following the initial conference, the case was reassigned to Judge Peter Leisure. When Judge Leisure recused himself shortly after receiving the assignment, the case was assigned to Judge Allen Schwartz.

On January 22, 1996, Judge Schwartz held a pretrial conference and set a schedule for motions. Cyanamid moved for summary judgment, contending that: (1) plaintiffs' claims were time-barred; (2) plaintiffs lacked standing; and (3) the district court lacked subject matter jurisdiction.

On June 26, 1997, while the summary judgment motion was still pending, the case was reassigned to Judge Robert Sweet. Judge Sweet scheduled a conference for November 5, 1997. Before this conference could occur, however, the case was reassigned to Judge Denise Cote. On November 5, 1997, Judge Cote granted Cyanamid's motion for summary judgment. By Opinion and Order, Judge Cote held that: (1) Craven's claims on behalf of herself and Brian Stuart were time- barred under Nebraska's ten-year statute of repose for product liability actions; and (2) the Kairdolfs' claims were time-barred under Louisiana's one- year statute of limitations for tort actions. Because Judge Cote found that all claims were barred by the relevant statutes of limitations and repose, she declined to address Cyanamid's claims that the court lacked subject matter jurisdiction or that plaintiffs lacked standing. Craven and the Kairdolfs now appeal.

DISCUSSION

I. Standard of Review

This Court reviews Judge Cote's grant of summary judgment

de novo, viewing all facts in the light most favorable to Craven and the Kairdolfs. See Bedoya v. Coughlin, 91 F.3d 349, 351 (2d Cir.1996).

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). A dispute regarding a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

II. Statutes of Limitations and Repose

A. Choice-of-Law Rules

Where jurisdiction rests upon diversity of citizenship, a federal court sitting in New York must apply the New York choice-of-law rules and statutes of limitations. See Guaranty Trust Co. v. York, 326 U.S. 99, 108- 09, 65 S.Ct. 1464, 89 L.Ed. 2079 (1945); Klaxon Co. v. Stentor Elec. Mfg. Co., ***627** 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). New York courts generally apply New York's statutes of limitations, even when the injury giving rise to the action occurred outside New York. See Stafford v. International Harvester Co., 668 F.2d 142, 147 (2d Cir.1981). This general rule, however, is subject to a traditional statutory exception, New York's "borrowing" statute, C.P.L.R. § 202.

Under C.P.L.R. § 202, when a nonresident plaintiff sues upon a cause of action that arose outside of New York, the court must apply the shorter limitations period, including all relevant tolling provisions, of either: (1) New York; or (2) the state where the cause of action accrued. See N.Y.C.P.L.R. § 202 (McKinney 1990). For purposes of C.P.L.R. § 202, a cause of action sounding in negligence or product liability accrues in the state where the injury occurs. See Dugan v. Schering Corp., 86 N.Y.2d 857, 635 N.Y.S.2d 164, 165, 658 N.E.2d 1037 (N.Y.1995); *Besser v. E.R. Squibb & Sons, Inc.*,

146 A.D.2d 107, 539 N.Y.S.2d 734, 736 n. 3 (1st Dep't 1989) (citations omitted), *aff'd*, 75 N.Y.2d 847, 552 N.Y.S.2d 923, 552 N.E.2d 171 (N.Y.1990). Hence, an action by a nonresident on a foreign cause of action is untimely if it is barred under the law of either New York or the state where the injury occurred.

B. *The Craven/Stuart Claims*

1. *Applicability of Nebraska's Statute of Repose*

Under Neb.Rev.Stat. § 25-224(1), "[a]ll product liability actions, ... shall be commenced within four years next after the date on which the death, injury, or damage complained of occurs." Neb.Rev.Stat. § 25- 224(1) (1995). There is an outside limit, however, imposed by subsection (2) of the same statute; it provides that any product liability action must "be commenced within ten years after the date when the product which allegedly caused the personal injury, death, or damage was first sold or leased for use or consumption." *Id. § 25-224*(2). Because subsection (2) bars an action for injuries occurring more than ten years after a product is marketed, it is properly viewed as a statute of repose, rather than a statute of limitations. *See Gillam v. Firestone Tire & Rubber Co.*, 241 Neb. 414, 489 N.W.2d 289, 291 (Neb.1992).

Generally speaking, a statute of limitations establishes the time period within which lawsuits may be commenced after a cause of action has accrued. See 51 Am.Jur.2d *Limitation of Actions* § 13 (1993). It is an affirmative defense, affecting the remedy, but not the existence of the underlying right. *See Paver & Wildfoerster v. Catholic High Sch. Ass'n*, 38 N.Y.2d 669, 382 N.Y.S.2d 22, 25, 345 N.E.2d 565 (N.Y.1976). In contrast, a statute of repose extinguishes the cause of action, the right, after a fixed period of time, usually measured from the delivery of the product or completion of work, regardless of when the cause of action accrued. *See* 1 Calvin W. Corman, *Limitation of Actions* § 1.3.2 (1991). Thus, a statute of repose may bar commencement of an action even before the cause of action accrues. Similarly, a plaintiff may be barred from bringing an action because the statute of repose has run, even though the applicable statute of limitations has not yet expired.

Neither this court, nor the New York Court of Appeals, has addressed whether C.P.L.R. § 202 applies when the "borrowed" statute happens to be a statute of repose, rather than a statute of limitations. Both the Appellate Division, First Department and the United States District Court for the Southern District of New York have concluded that C.P.L.R. § 202 applies to both without distinction. *See Barnett v. Johnson*, 839 F.Supp. 236, 239 (S.D.N.Y.1993); *Ledwith v. Sears Roebuck & Co.*, 231 A.D.2d 17, 660 N.Y.S.2d 402, 406 (1st Dep't 1997). These courts have reasoned that the purpose of the borrowing statute--preventing forum shopping by plaintiffs seeking the holy grail of the longer period--is best served by applying the period of the foreign state, regardless of how it is denominated.

Neither party challenges Judge Cote's application of Nebraska's statute of repose. Accordingly, we see no need to consider whether the New York Court of Appeals ***628** would agree that a statute of repose would be borrowed under C.P.L.R. § 202.

2. *Timeliness of the Craven/Stuart Action*

[13] Judge Cote correctly determined that Pamela Craven's and Brian Stuart's claims are barred by Nebraska's ten-year statute of repose. The statute begins to run when the product is "first sold or leased for consumption." Neb.Rev.Stat. § 25-224(2) (1995); see Gillam, 489 N.W.2d at 291. The latest date that the time period began to run was March 19, 1979, the date that Brian Stuart was inoculated with the Orimune vaccine. See Witherspoon v. Sides Constr. Co., 219 Neb. 117, 362 N.W.2d 35, 39-41 (Neb.1985) (statute of repose begins to run when product received by ultimate consumer); Fritchie v. Alumax Inc., 931 F.Supp. 662, 674 (D.Neb.1996). Therefore, Cyanamid became immune to suit no later than March 19, 1989. Because Craven did not commence the action until 1995, the Craven claims are clearly time-barred.

Craven contends that Judge Cote erred because: (1) Cyanamid's fraudulent concealment tolled the statute of repose; (2) Cyanamid conceded that its fraudulent concealment tolled the statute of repose; (3) Brian's claims are not untimely because the statute of

repose was tolled during Brian's infancy; and (4) their claims for breach of warranty are timely.

[14][15][16][17] Craven's contention that Cyanamid's fraudulent concealment tolled the statute of repose is without merit. A defendant who fraudulently conceals "a material fact necessary to the accrual of a cause of action against him" may indeed be equitably estopped from raising Nebraska's statute of repose as a defense. *See Schendt v. Dewey*, 246 Neb. 573, 520 N.W.2d 541, 548 (Neb.1994) (per curiam). To establish fraudulent concealment, however, a plaintiff must show that: (1) "he or she exercised due diligence to discover his or her cause of action" before the relevant time period expired; and (2) the defendant concealed "any facts which would have put [the plaintiff] on notice of any cause of action." *Upah v. Ancona Bros. Co.*, 246 Neb. 585, 521 N.W.2d 895, 902 (Neb.1994). When the "means of knowledge [are] at hand to put the plaintiff on inquiry of any cause of action she might have had against the defendants," a plaintiff cannot claim fraudulent concealment. *Id.* at 905.

Craven asserts that the statute of repose is tolled because Cyanamid concealed that the Orimune vaccine received by Brian did not meet federal regulatory requirements. Even if true, this argument does not help plaintiffs. Cyanamid's failure to disclose its failure to meet regulatory requirements did not prevent Craven from being put on notice of a claim against Cyanamid. Craven knew in 1979 that Brian Stuart was injured and that this injury was related to the ingestion of Orimune. As Judge Cote noted, "thirteen or fourteen" doctors advised her in 1979 that Brian's condition was related to the ingestion of Orimune. Moreover, that same year an attorney advised her that she "had a case." Because Craven had sufficient information to put her on notice of a claim in 1979, she cannot rely on the doctrine of fraudulent concealment to toll the statute of repose.

Craven's argument that Cyanamid "conceded" that the fraudulent concealment tolled the statute of repose is also without merit. Craven asserts that when Cyanamid conceded, for the purpose of the summary judgment motion, that the facts in the Craven/Stuart/Kairdolf complaint were true, Cyanamid also conceded the complaint's legal conclusion that Cyanamid's fraudulent

concealment tolled the statute of repose. We disagree. We read Cyanamid's "concession" to be nothing more than an acknowledgment that, for purposes of the summary judgment motion, no genuine issues of material fact existed. Cyanamid did not concede the legal conclusions that plaintiffs sought to draw from the undisputed facts.

Carven's [sic] attempt to toll the Nebraska statute during Brian's infancy is also unavailing. The statute of repose (which was adopted well after the infancy tolling provision was enacted) bars all product liability actions commenced more than ten years after the product's sale "[n]otwithstanding ... [any] other statutory provision to the contrary...." Neb.Rev.Stat. § 25- 224(2) (1995). In light of the unambiguous language of the ***629** statute, it is clear that the Nebraska legislature did not intend to toll the statute of repose during a claimant's infancy. See 2 Calvin W. Corman, *Limitation of Actions* § 9.7.2, at 72 (1991) ("Statutes of repose, unlike statutes of limitations, are drafted in absolute terms with the apparent legislative intent to preclude all forms of postponement of the accrual date of the cause of action.").

Finally, Craven's attempt to recast her cause of action as one for breach of express warranty under U.C.C. § 2-725 (which is specifically exempted from Nebraska's statute of repose) also fails. Section 2-725 provides that "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued." Neb.Rev.Stat. U.C.C. § 2-725 (1993). A cause of action accrues "when tender of delivery is made." *Id.*

Whether the action is governed by Nebraska's product liability statutes of limitations and repose, or the U.C.C. statute of limitations, "is determined by the nature of the complaint, not the form of the pleadings, and consideration must be given to the facts which constitute the cause of action." *Thomas v. Countryside of Hastings, Inc.*, 246 Neb. 907, 524 N.W.2d 311, 313 (Neb.1994) (citing *Lincoln Grain v. Coopers & Lybrand*, 216 Neb. 433, 345 N.W.2d 300 (1984)); *see Fritchie*, 931 F.Supp. at 672 (U.C.C. 2- 725 does not apply "[w]here the claims are pre-dominantly tort-like in nature, ... rather than principally contractual in nature" (citation omitted)). Professors Summers and White suggest that courts facing

this inquiry typically examine "the nature of the injury, the language of the complaint, and whether the parties are in privity of contract." 1 James White & Robert Summers, *Uniform Commercial Code* § 11-9, at 606 (4th ed.1995).

We agree with Judge Cote that Craven's claims are predominantly tortious in nature and are therefore governed by Nebraska's product liability statute. First, Craven seeks both compensatory and punitive damages for Brian's physical injuries, pain, and suffering. Personal injury damages, especially punitive damages, suggest more tort than contract. *See, e.g., Follette v. Wal-Mart Stores*, 41 F.3d 1234, 1236 (8th Cir.1994). Moreover, Brian Stuart and Craven were not in privity with Cyanamid since Brian received the vaccine from his doctor, not Cyanamid. The absence of a direct contractual relationship between Cyanamid and the claimants further compels the conclusion that the product liability statute applies. *See Fritchie*, 931 F.Supp. at 672; *see also Pirri v. Toledo Scale Corp.*, 619 A.2d 429, 431 (R.I.1993).

We find additional support in Nebraska's broad definition of product liability actions. The Nebraska legislature defined product liability actions to encompass:

> any action brought against a manufacturer, seller or lessor of a product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formulation, installation, preparation, assembly, testing, packaging, or labeling of any product, or the failure to warn or protect against a danger, or hazard, in the use, misuse, or intended use of any product, or the failure to provide proper instructions for the use of any product.

Neb.Rev.Stat. § 25-21, 180 (1995). Because Craven seeks "personal injury" damages due to Cyanamid's faulty "manufacture," "preparation," and "testing" of Orimune, her claims constitute a "product liability" action subject to Nebraska's statute of repose. *See Follette*, 41 F.3d at 1236 (breadth of Arkansas' product liability

statute mandated application of product liability statute of limitations, rather than U.C.C. limitations period).

Since Craven's claims are barred by the Nebraska statute of repose, the law of the state where the cause of action accrued, the action is time-barred in a New York federal court sitting in diversity. See N.Y.C.P.L.R. § 202 (McKinney 1990).

C. *The Kairdolf's Claims*

1. *Louisiana Laws of Prescription*

The parties agreed below, and do not challenge on appeal, that Louisiana's laws of prescription (i.e., statutes of limitations) govern the Kairdolfs' claims under C.P.L.R. § 202.

***630** 2. *Timeliness of the Kairdolf action*

The Kairdolfs assert that Judge Cote erred when she dismissed their claims because: (1) Louisiana rules of prescription do not apply where the causal relationship between the product and the injury is not immediately discoverable; and (2) they have an independent cause of action under "redhibition." They are wrong.

Louisiana's "delictual" or tort prescription period bars actions brought more than one year from "the day injury or damage is sustained." La.Civ.Code Ann. art. 3492 (1988). The one-year period begins to run when the plaintiff "has a reasonable basis to pursue a claim against a specific defendant." *Jordan v. Employee Transfer Corp.*, 509 So.2d 420, 423- 24 (La.1987). Where "allegations of medical causation are vital to the cause of action," prescription does not run until plaintiff has "actual or constructive notice of the causal connection between the medical treatment and the subsequent condition." *Sharkey v. Sterling Drug, Inc.*, 600 So.2d 701, 713 (La.Ct.App.1992) (citations omitted). Such "constructive knowledge" exists when plaintiff has "sufficient information to incite curiosity, to excite attention, or to put a reasonably minded person on guard and call for inquiry." *Gassen v. East Jefferson Gen. Hosp.*, 687 So.2d 120, 124 (La.Ct.App.1996) (citing *White v. Willis-Knighton Med. Ctr.*, 632 So.2d 1198, 1199 (La.Ct.App.1994)).

Judge Cote properly found that the Kairdolfs had notice of the causal connection between Cyanamid's vaccine and Michella's polio no later than March 1987. In 1991, acting on behalf of Michella, the Kairdolfs filed a petition for relief under the VCA. The Kairdolfs submitted an affidavit to the United States Court of Claims, swearing that "Dr. Bennett diagnosed Michella as suffering from post-polio reaction to the OPV given her at the age of two (2) months. This diagnosis was made on March 17, 1987." Therefore, it is clear that the Kairdolfs knew the cause of Michella's injury in March 1987. Accordingly, the one-year prescription period expired in March 1988, seven years before the Kairdolfs commenced this action.

Nor can the Kairdolfs survive summary judgment by recasting their claim as one for "redhibition." "Redhibition is the avoidance of a sale on account of some vice or defect of the thing sold, rendering it either absolutely useless, or its use so inconvenient and imperfect that it must be supposed that the buyer would not have purchased it, had he known of the vice." La.Civ.Code Ann. art. 2520 (1985). "In a suit for redhibition, the plaintiff must prove: (1) the seller sold the thing to him and it is either absolutely useless for its intended purpose or its use is so inconvenient or imperfect that, judged by the reasonable person standard, had he known of the defect, he would never have purchased it; (2) the thing contained a non- apparent defect at the time of sale; and (3) the seller was given an opportunity to repair the defect." *Jackson v. Slidell Nissan*, 693 So.2d 1257, 1262 (La.Ct.App.1997) (citing *Vincent v. Hyundai Corp.*, 633 So.2d 240, 243 (La.Ct.App.1993), *writ denied*, 634 So.2d 832 (La.1994)). There are several problems with plaintiffs' attempt to invoke the Roman Law doctrine of redhibition.

First of all, the ingestion of Orimune was not a "sale" under the redhibition statute. A "sale" is "a contract whereby a person transfers ownership of a thing to another for a price in money." La.Civ.Code Ann. art. 2439 (1985). The medical administration of Orimune to Michella by her doctor cannot fairly be considered a "sale" under Louisiana law. See Martin v. Earl J. Rome, Jr., D.D.S., 486 So.2d 213, 215-16 (La.Ct.App.1986).

Moreover, even if the Kairdolfs could cobble together some

kind of redhibition claim, the claim would still be untimely. Claims in redhibition have various prescriptive periods, depending on whether the seller was aware of the defect at the time of sale. Pursuant to La.Civ.Code Ann. art. 2534 (1985), the time limit on an action for redhibition depends upon what the seller, not the buyer, knew. An action for redhibition against a seller who did not know of the defect's existence must be commenced within one year from the date of delivery to the buyer. Id. art. 2534 A. However, if the seller knew, or if he is presumed to have ***631** known, of the defect, the action for redhibition must be commenced within one year from the day the defect was discovered by the buyer. Id. art. 2534 B. When the seller is a manufacturer, it is conclusively presumed to have known of a defect in the product it produced. La.Civ.Code Ann. art. 2545 (1985); *Alexander v. Burroughs Corp.*, 359 So.2d 607, 609 (La.1978). Since Cyanamid is thus presumed to have known of Orimune's defect at the time of sale, the Kairdolfs had to commence their action within one year after they discovered that Orimune was defective.

A buyer discovers a defect, and the prescription begins to run, when there is sufficient notice to call for inquiry about a claim. *See Maison Blanche, Inc. v. Louisiana Dep't of Labor, Office of Employment Sec.*, 604 So.2d 670, 674 (La.Ct.App.), *writ denied*, 608 So.2d 178 (La.1992). The Kairdolfs became aware of Orimune's defect in 1987 when Michella was diagnosed as having vaccine-induced polio. At that time, the Kairdolfs knew the extent of Michella's injury and that the injury was caused by her ingestion of Orimune. Thus, the one-year prescriptive period expired in 1988, well before the Kairdolfs commenced this litigation in 1993.

The Kairdolfs contend that it was only in 1993, when the United States Court of Appeals for the Fourth Circuit held that Orimune violated federal regulations, that they had any reason to suspect that Orimune was defective. This argument is unpersuasive. The prescriptive period for a redhibition action begins to run from the date that the defect is manifest, not from when the plaintiff discovers the actual cause of the defect. *See Beth Israel v. Bartley, Inc.*, 579 So.2d 1066, 1073 (La.Ct.App.1991); *Lee v. Equitable Life Assurance Soc'y of U.S.*, 391 So.2d 37, 39 (La.Ct.App.), *writ denied*, 395 So.2d 1363 (La.1981).

Since the Kairdolfs' claims are barred under Louisiana law, the state where their cause of action accrued, they are also time-barred in a New York federal court sitting in diversity. *See* N.Y.C.P.L.R. § 202 (McKinney 1990).

CONCLUSION

We have considered all the arguments raised by appellants and find them to be without merit. Accordingly, the judgment of the district court is AFFIRMED.

OPINION OF THE SOUTHERN DISTRICT BELOW
(Cite as: 1997 WL 695578 (S.D.N.Y.))

Brian Keith STUART, a minor, by his natural guardian and next friend Pamela Jean Craven; Pamela Jean Craven; Paula Kairdolf and Erroll M. Kairdolf, as parents and natural guardians of Michella Renee Kairdolf, a minor; Paula Kairdolf, individually; and Erroll M. Kairdolf, Plaintiffs,

v.

AMERICAN HOME PRODUCTS CORPORATION and American Cyanamid Company, a wholly owned subsidiary of American Home Products Corporation, Defendants.

No. 95 CIV. 4940(DLC).

United States District Court, S.D. New York.

Nov. 6, 1997.

Kreindler & Kreindler, By Marc S. Moller, Esq., New York, New York, for Plaintiffs.

Kops and Fenner, P.C., By Stanley P. Kops, Esq., Philadelphia, Pennsylvania, for Plaintiffs.

Donovan Leisure Newton & Irvine, By Daniel J. Thomasch, Esq., Christopher P. Johnson, Esq., New York, New York, for Defendants.

OPINION AND ORDER

COTE, District J.

*1 This case arises out of injuries sustained by plaintiffs Brian Keith Stuart and Michella Kairdolf as a result of their vaccination with Orimune, a live oral polio vaccine ("OPV") manufactured by defendant American Cyanamid Company ("Cyanamid"), a wholly owned subsidiary of defendant American Home Products ("AHP"), [FN1] and licensed by the federal government for distribution to the public in the early 1960's. The Stuart action includes a representative action brought on behalf of Brian Stuart by his mother, Pamela Craven, and an action brought individually by Craven. The Kairdolf action involves a representative action brought on behalf of Michella Kairdolf by her parents Paula and Erroll Kairdolf and actions brought individually by Paula and Erroll Kairdolf. [FN2]

> FN1. AHP was not properly served when this action was initiated.

> FN2. In October 1995, when this case was still before Judge Miriam G. Cedarbaum, plaintiffs moved for class certification pursuant to Rule 23, Fed.R.Civ.P., but withdrew this motion one month later. Subsequently, the case was transferred several times and was assigned to this Court in July 1997.

Plaintiffs allege six claims for relief: (1) strict liability, (2) fraud, (3) negligence, (4) breach of implied warranty of merchantability, (5) breach of implied warranty of fitness for a particular purpose, and (6) breach of express warranty of fitness for a particular purpose. The common theme of plaintiffs' claims is that Cyanamid sold Orimune even though it knew or should have known that Orimune is a defective product that should not have been licensed by the Government, a fact plaintiffs claim was concealed until 1993.

Cyanamid moves for summary judgment on the grounds that (1) plaintiffs' claims are barred by the applicable statutes of limitation, (2) plaintiffs lack standing, and (3) the Court lacks subject matter jurisdiction over plaintiffs' claims insofar as they

allege regulatory violations. [FN3] For the reasons stated below, Cyanamid's motion for summary judgment is granted.

> FN3. Because plaintiffs' claims are entirely barred by the relevant statutes of limitations, I do not address defendants' arguments with regard to partial summary judgment based on an absence of subject matter jurisdiction. See Cantor Fitzgerald, L.P. v. Peaslee, 88 F.3d 152, 155 (2nd Cir.1996) (a federal court may "avoid a difficult question of subject- matter jurisdiction when the case may be disposed of on a simpler ground").

FACTS

There is no material dispute with regard to the following facts.

In 1955, Dr. Jonas Salk developed a vaccine against poliomyelitis, a disease of the central nervous system. The Salk vaccine was an inactivated polio vaccine ("IPV") derived from a virus which had been killed. In Re Sabin Oral Polio Vaccine Prods. Liab. Litig., 763 F.Supp. 811, 814 (D.Md.1991), aff'd, 984 F.2d 124 (4th Cir.1993). The Salk vaccine decreased the incidence of polio but did not eradicate it. Id.

In 1958, the United States Government began to investigate the possibility of developing an oral polio vaccine ("OPV"). Id. In 1960, the Surgeon General declared that OPV was suitable for use in the United States and in 1961, the Division of Biologic Standards of the National Institutes of Health ("DBS") adopted regulations governing the issuance of manufacturing licenses and the approval and release of OPV. Id. In 1960, Cyanamid purchased strain material that had been developed by Dr. Albert Sabin and applied to DBS for a license to manufacture an OPV. Id. at 815. In 1962, the DBS licensed Cyanamid to manufacture and sell OPV. Since 1963, Cyanamid has distributed an OPV product under the trade name Orimune and since 1977, Cyanamid has been the sole supplier of OPV in the United States.

*2 Although the OPV program has resulted in the virtual eradication of wild poliovirus in the Western Hemisphere, there is an inherent risk in the use of OPV. Id. at 813. Like other live virus vaccines, OPV stimulates immunity by inducing a mild infection in vaccinees. Thus, there is a risk that a person vaccinated with OPV may develop polio. Id. at 814.

In January 1993, in an action against the United States under the Federal Torts Claim Act ("FTCA") for damages allegedly resulting from administration of Orimune, the Fourth Circuit affirmed a district court's finding that DBS had violated certain federal regulations regarding the testing of vaccines in releasing Orimune to the public. [FN4] In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 984 F.2d 124, 127 (4th Cir.1993). This ruling subjected the United States to liability under the FTCA to plaintiffs who could prove injuries caused by the Government's improper approval of Orimune. In re Sabin, 763 F.Supp. at 829. As an alternative to private litigation under the FTCA, recovery for injuries caused by the administration of Orimune is available under the National Childhood Vaccine Injury Compensation Act ("VCA"), which authorizes compensation for specified injuries, including polio, when caused by a covered vaccine. 42 U.S.C. §§ 300aa-10(a), 11(c)(1), 14(a) (1991). In the instant case, both plaintiffs first filed claims under the VCA only to withdraw them in favor of this lawsuit, which alleges that Cyanamid should have known that the Government's approval of Orimune was improper and should not have marketed the vaccine to the public.

> FN4. Specifically, the Fourth Circuit affirmed the district court's finding that DBS, in approving Orimune, violated 42 C.F.R§ 73.113(b) (1991), which requires that virus in a live vaccine "shall represent no more than five tissue culture passages from the original strain" by releasing vaccine lots that were more than five tissue cultures from the original Sabin strain. The Fourth Circuit also affirmed the district court's finding that DBS had violated 42 C.F.R. § 73.114(b)(1)(iii) (1991), by releasing vaccine lots that impermissibly exceeded the potency of the reference

poliovirus approved by the National Institute of Health. In Re Sabin, 984 F.2d at 126-27.

The key events in the two actions that pertain to the statute of limitations issues are as follows:

The Stuart Action

12/9/78: Brian Stuart is born in Nebraska.

3/19/79: Stuart receives administration of Orimune at University of Nebraska Medical Center Clinic.

4/79: Stuart develops a paralytic condition.

5/79: Doctors tell Stuart's mother that it is "99 percent" certain that
Brian's paralysis was caused by a vaccine induced polio infection.

5/79: Craven retains an attorney, who advised her that she "had acase."

9/27/90: A petition is filed on Brian Stuart's behalf in the United States Court of Claims under the the VCA seeking compensation from the federal government for Brian Stuart's paralytic condition.

9/25/94: Craven withdraws the VCA petition, effective Novembe r 25, 1994.

6/29/95: Craven files suit against Cyanamid.

The Kairdolf Action

11/22/82: Michella Kairdolf is born in Louisiana.

1/21/83: Michella Kairdolf is administered Orimune at the office

of her pediatrician, Dr. James Michalik.

2/83: Michella Kairdolf
develops a paralytic condition. Dr. Michalik
suspects that Michella Kairdolf might be suffering from polio.

8/84: Michella Kairdolf is evaluated by the Centers for Disease Control("CDC") and diagnosed as suffering from vaccine induced polio.

3/17/87: As reflected in a 1991 affidavit filed by the Kairdolfs, M ichella Kairdolf is diagnosed with polio by Dr. James Bennett.

1/31/91: A petition is filed on Michella Kairdolf's behalf under th e VCA in
the United States Court of Claims, seeking compensation from the federal government for her alleged vaccine-related injuries.

10/24/94: The Kairdolfs withdraw the VCA petition, effective Oct ober 24, 1994.

6/29/95: The Kairdolfs file suit against Cyanamid.

DISCUSSION

*3 Summary judgment is appropriate if the evidence offered demonstrates that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact and all inferences and ambiguities are resolved in favor of the party against whom summary judgment is sought. Gallo v. Prudential Residential Servs., Ltd. Partnership, 22 F.3d 1219 (2d Cir.1994).

In a diversity action such as this, a federal court must

apply the substantive law of New York. Erie Railroad v. Tompkins, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). Under New York law, since the statute of limitations is considered procedural, New York applies its own statute of limitations even when the injury which gives rise to the action has occurred in another state. Stafford v. International Harvester, 668 F.2d 142, 147 (2d Cir.1981). New York's borrowing statute, Section 202 of the Civil Practice Law and Rules ("CPLR") (McKinney 1990), provides that in the case of a cause of action accruing outside of New York, the court must apply the shorter limitation period of either (a) New York or (b) the state in which the cause of action arose. Id. at 147-48. The parties do not dispute that the statutes of limitation for Nebraska and Louisiana apply to the Stuart and Kairdolf claims, respectively.

The Stuart Action

While Nebraska law generally provides a four year statute of limitations period from the date of injury for product liability claims, there is a complete ban on claims filed ten years after the product was first sold for consumption. The Nebraska statute of limitations provides that

> [a]ll product liability actions shall be commenced within four years next after the date on which the death, injury or damage complained of occurs.

Neb.Rev.Stat. § 25-224(1) (1981) (emphasis supplied). The Nebraska statute of repose provides that

> [n]otwithstanding subsection (1) of this section or any other statutory provision to the contrary, any product liability action, except one governed by section 2-725, Uniform Commercial Code, shall be commenced within ten years after the date when the product which allegedly caused the personal injury, death, or damage was first sold or leased for use or consumption.

Neb.Rev.Stat. § 25-224(2) (1981) (emphasis supplied).

Thus, while the statute of limitations measures a deadline

for filing from the date a cause of action accrued, the statute of repose measures the deadline from the date the product was first sold. Therefore, an action could be barred by the statute of repose before any injury has been sustained. Miers v. Central Mine Equip. Co., 604 F.Supp. 502, 505 (D.Neb.1985). The statute of repose, therefore, has been understood by courts to affect substantive rights. Id.

Brian Stuart received the vaccine in March 1979 and developed paralysis by May 1979. This lawsuit, however, was not filed until June 1995, some sixteen years later. Under the Nebraska statute of repose, the Stuart claims were time barred no later than March 1989, ten years after Brian received his dosage of the vaccine and six years before this lawsuit was filed. Plaintiffs offer five arguments as to why the Stuart and Craven actions are nevertheless timely.

*4 First, plaintiffs argue that Nebraska's infant tolling statute, which tolls actions until a child is 20 years old, applies to the ten year period under the statute of repose. [FN5] The statute of repose, which was adopted long after the infant tolling provision, begins with the language "Notwithstanding... any other statutory provision to the contrary...." Given this explicit and unambiguous language, the statute of repose is not tolled by the infant tolling statute. Both of the cases on which the plaintiffs rely address the interplay between the infancy tolling statute and other statutes which do not contain the broad exclusion of the statute of repose. See Macku v. Drackett Prods., 216 Neb. 176, 343 N.W.2d 58, 61 (Neb.1984) (construing Neb.Rev.Stat. § 25-224(4)); Sacchi v. Blodig, 215 Neb. 817, 341 N.W.2d 326 (Neb.1983) (construing Neb.Rev.Stat. § 25-222).

FN5. The infant tolling statute provides:
[I]f a person entitled to bring any action mentioned in this chapter ... is, at the time the cause of action accrued, within the age of twenty years, ... such person shall be entitled to bring such action within the respective times limited by

> this chapter after such disability is removed.

Neb.Rev.Stat. § 25-213 (1988). The infant tolling statute does not apply to Craven's claims. See Macku v. Drackett Prods., 216 Neb. 176, 343 N.W.2d 58, 62 (Neb.1984).

Relying on Miers, 604 F.Supp. 502, plaintiffs next argue that the statute of repose does not bar Brian Stuart's claim because he was injured before the ten-year limitation of the statute of repose expired. To the contrary, according to Miers, if an injury occurs more than ten years after a product is sold, the statute of repose operates to deny the plaintiff any cause of action, and if an injury occurs fewer than ten years after the sale, the statute of repose shortens the statute of limitations to the point at which the period of repose expires. Id. at 506. Accordingly, Miers provides no escape from the statute of repose.

Third, plaintiffs argue that the Craven and Stuart actions are both subject to equitable tolling because Cyanamid allegedly fraudulently concealed the dangers of Orimune until 1993. Although the statute of repose is not subject to tolling by any other statutory provision, it is not available as a defense if the defendant has engaged in fraudulent concealment. MacMillen v. A.H. Robins Co., 217 Neb. 338, 348 N.W.2d 869, 871 (Neb.1984). In order to assert fraudulent concealment under Nebraska law,

> the plaintiff must show that he or she exercised due diligence to discover his or her cause of action before the statute of limitations expired and that the defendant committed some affirmative act of fraudulent concealment which prevented the plaintiff from discovering his or her cause of action. Unless there is a fiduciary relationship between the parties, mere silence is not enough to overcome the applicable period of limitation.

Upah v. Ancona Bros. Co., 246 Neb. 585, 521 N.W.2d 895, 902 (Neb.1994). Plaintiffs cannot meet this high standard.

The plaintiffs discovered the injury and its cause in 1979.

In that year, "thirteen or fourteen doctors" advised Brian Stuart's mother that Brian's condition was OPV-induced polio and an attorney counseled her that she "had a case." Nevertheless, plaintiffs chose to wait to file suit until long after the expiration of the period for both the ordinary statute of limitations as well as the statute of repose. Moreover, plaintiffs have failed to provide evidence of any affirmative act of fraudulent concealment by Cyanamid. The only evidence of wrongdoing offered by the plaintiffs concerns the government's improper approval of Orimune, not fraud by Cyanamid. As a consequence, the doctrine of equitable tolling can not be effectively invoked by the plaintiffs to avoid the statute of repose. See id. at 905 (When the "means of knowledge [are] at hand to put the plaintiff on inquiry as to any cause of action she might have had against the defendants," a plaintiff cannot claim fraudulent concealment.).

*5 Plaintiffs next seek to place their claims within the sole exception to the broad sweep of Section 25-224(2) and characterize them as actions covered by the express warranty provision of U.C.C. § 2-725. The U.C.C. provides that "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued." Neb.Rev.Stat. U.C.C. § 2-725. It further explains that a "cause of action accrues ... when tender of delivery is made." Id.

In this case, there was no "sale" of Orimune nor a "tender of delivery" by the defendants to plaintiffs, only a medical administration of Orimune to Brian Stuart by a physician. Plaintiffs may not make an "end-run" around the statute of repose by recasting their products liability action as a U.C.C. action. To begin with, Nebraska law defines a product liability action broadly to include:

> any action brought against a manufacturer, seller, or lessor of a product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction,

> design, formulation, installation, preparation, assembly, testing, packaging, or labeling of any product, or the failure to warn or protect against a danger or hazard in the use, misuse or intended use of any product, or the failure to provide proper instructions for the use of any product. (emphasis supplied).

Neb.Rev.Stat. § 25-21,180. At least one federal court has refused to apply the U.C.C. exception to the statute of repose in similar circumstances. In Groth v. Sandoz, 601 F.Supp. 453 (D.Neb.1984), the plaintiff had been injured through a medically administered drug and brought an action against the manufacturer for breach of implied and express warranty. The court noted that the action was "[c]learly ... in the nature of [a] product liability action," id. at 455, and held that the U.C.C. exception to the statute of repose was "not applicable." Id. at 454 n. 1.

Plaintiffs' final argument is that the claim for fraud, which carries a ten year statute of limitations, is timely since a cause of action for fraud does not accrue until the fraud is discovered, which in this case occurred in 1993, when the Fourth Circuit issued its decision in Sabin. Plaintiffs' argument is unavailing. A limitations period runs from the time that the plaintiff is on notice of the facts giving rise to the claim, not the point at which her attorneys first discover an additional legal theory upon which to seek redress for the injury. See Upah, 521 N.W.2d at 902. In this case, Craven was on notice of her right to bring an action in 1979 and the statute of limitations began to run at that point. However plaintiffs attempt to dress their legal theories, under Section 25-21,180 of the Nebraska Revised Statutes, which defines a product liability action as "any action brought against a manufacturer... regardless of the substantive legal theory ... upon which the action is brought, for or on account of personal injury," the action remains a product liability action governed by the ten-year limitation of the statute of repose.

The Kairdolf Actions

*6 Cyanamid argues that the Kairdolf individual and derivative actions are barred by Louisiana's one year statute of limitations. That statute provides:

> delictual [FN6] actions are subject to a liberative prescription of one year. This prescription commences to run from the day injury or damage is sustained.
>
> FN6. Black's Law Dictionary defines a "delict" as a "criminal offense," "tort" or "wrong." Black's Law Dictionary 427 (6th ed.1990).

La. Civ.Code Ann. art. 3492 (1994). The one year period begins to run, however, only when the plaintiff has "a reasonable basis to pursue a claim against the defendant." See Jordan v. Employee Transfer, 509 So.2d 420, 423-24 (La.1987). In cases in which "allegations of medical causation are vital to the cause of action," "prescription does not run until the plaintiff has actual or constructive notice of the causal connection between the medical treatment and the subsequent condition." Sharkey v. Sterling Drug, Inc., 600 So.2d 701 (La.Ct.App.1992). Thus,

> [w]hen a party has sufficient information to incite curiosity, to excite attention, or to put a reasonably minded person on guard and call for inquiry, he has the constructive knowledge necessary to start the running of prescription.

Gassen v. East Jefferson Gen. Hosp., 687 So.2d 120, 124 (La.Ct.App.1996). *See also Kambitsis v. Schwegmann Giant Supermarkets, Inc.*, 665 So.2d 500, 502 (La.Ct.App.1995), *cert. denied*, 65 U.S.L.W. 3265 (1996) ("Information or knowledge suggesting an inquiry is sufficient to start the running of prescription."). Cyanamid contends that the one year prescriptive period began to run in March 1987. [FN7]

> FN7. In 1992, Louisiana added to Article 3492 a tolling

provision for minors with product liability claims. The parties agree that this tolling provision does not apply retroactively to revive causes of action that were time barred as of 1992. Chance v. American Honda Motor Co., 635 So.2d 177, 178 (La.1994).

Plaintiffs appear to raise two arguments as to why the Kairdolf actions are still timely.

(1) Date of Discovery

First, plaintiffs claim that they did not know for sure that Michella had polio until after 1991, [FN8] when they discovered a document from the CDC which indicated that it had diagnosed Michella as having vaccine induced polio in August 1984. [FN9] Since the filing of the VCA petition in 1991 tolls the limitations period until the petition is withdrawn, see 42 U.S.C. § 300aa- 16(c) (1991), this action--which was filed approximately six months after the VCA claim was withdrawn--is timely if the Kairdolfs are correct as to the date of discovery. This argument, however, cannot succeed in the face of the Kairdolfs' own admission that they knew since March 1987 that their daughter had been diagnosed as suffering from polio induced by the vaccine.

FN8. Plaintiffs identify the date they received the CDC report only as some time "[d]uring the course of the VCA." The VCA claim was filed in January 1991 and withdrawn in October 1994.

FN9. Plaintiffs have offered no explanation as to how the CDC evaluated the 21-month-old Michella, and diagnosed her as suffering from polio, without her parents' knowledge. The fact that the CDC diagnosis was made in August 1984 strongly suggests that the Kairdolfs may have been on notice from the CDC of the exact nature of Michella's vaccine-induced condition at that time. Nevertheless, the Court accepts, as it must for purposes of Cyanamid's summary judgment motion, the Kairdolfs'

claim that they were completely ignorant of the CDC diagnosis until some point after January 1991.

In filing for compensation from the VCA in 1991, the Kairdolfs claimed that their daughter had been diagnosed as having polio on March 17, 1987. In an affidavit which was signed by both parents and which was submitted to the United States Court of Claims, they stated

> [u]pon review of all of Michella's medical records and x-rays, Dr. Bennett diagnosed Michella as suffering from post-polio reaction to the OPV given her at the age of two (2) months. This diagnosis was made on March 17, 1987. Heretofore, Affiants had been told and presumed that their daughter had suffered from meningitis....

*7 In opposition to this motion, the Kairdolfs have submitted an affidavit from the attorney who represented them in connection with the VCA claim, who asserts that he prepared the VCA affidavit without the participation of the Kairdolfs, based on his misunderstanding of Dr. Bennett's medical records. This affidavit is insufficient to create a material issue of fact as to the understanding of the plaintiffs. *See United States v. Private Sanitation Indus. Ass'n. of Nassau/Suffolk*, 44 F.3d 1082, 1084 (2d Cir.1994). Furthermore, Ms. Kairdolf admitted in her deposition that she signed the affidavit and reviewed it for accuracy prior to signing. Mr. Kairdolf conceded in his deposition that the affidavit stated the facts as he understood them at the time he signed it. Having sworn to the United States Court of Claims that Michella was diagnosed with polio in March 1987, and having affirmed that testimony in their depositions, the Kairdolfs cannot now create a fact issue by offering evidence to contradict their own prior sworn statements. *Raskin v. Wyatt*, No. 96-7570, 1997 WL 556063 (2d Cir. Sept.9, 1997); *Mack v. United States*, 814 F.2d 120, 124-25 (2d Cir.1987).

Plaintiffs also rely on the fact that Dr. Bennett testified in

his deposition that he did not diagnose Michella with polio in March 1987 and that his clinic notes refer to Michella's condition only as "Left-flaccid hemiplegia, almost polio-type, with a history of meningitis." There is, however, no dispute that Dr. Bennett discussed with the Kairdolfs in March 1987 the possibility that Michella's condition was vaccine-induced polio. This discussion, alone, was sufficient to give the Kairdolfs constructive notice of the connection between the medical treatment and the disease. Therefore, even without the existence of the VCA affidavit, which shows that the plaintiffs had actual knowledge in March 1987, of the cause of their daughter's affliction, the Kairdolfs' action would be barred under Louisiana law.

(2) Redhibition

The Kairdolfs also attempt to salvage their case by claiming that they have an independent cause of action under Louisiana law for "redhibition," which carries a one year statute of limitations from the date a defect is discovered by a buyer. Redhibition, which the plaintiffs have not pleaded in their complaint, is defined as follows:

> The seller warrants the buyer against redhibitory defects, or vices, in the thing sold.
>
> A defect is redhibitory when it renders the thing useless or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect. The existence of such a defect gives a buyer the right to obtain rescission of the sale.

A defect is redhibitory also, when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price. The existence of such a defect limits the right of a buyer to a reduction of the price.

*8 La. Civ.Code Ann. art. 2520 (West 1995). As noted,

there is a one year statute of limitations for a redhibition action from the date the buyer discovers a defect.

> The action for redhibition against a seller who knew, or is presumed to have known, of the existence of a defect in the thing sold prescribes in one year from the day the defect was discovered by the buyer.

La. Civ.Code Ann. art. 2534 (West 1995). Plaintiffs argue that their redhibition action is timely under Article 2534 because they discovered the Orimune defect in 1993 and filed the action less than one year after withdrawing their VCA claim. This argument is unpersuasive.

To begin with, plaintiffs have offered no authority for casting this action as an action for redhibition and, indeed, it is not an action for redhibition. As the statute makes clear, redhibition involves a warranty by the seller to the buyer that the item sold is free of defects or vices. In this case, there was no sale of Orimune by the defendants to plaintiffs, only a medical administration of Orimune to Michella Kairdolf by a physician. Even if the action were properly brought as an action for redhibition, however, it would be time barred. Whereas plaintiffs stated in their 1991 affidavit that they first became aware of their cause of action in March 1987, and, earlier in this litigation claimed that they first became aware of their cause of action upon reading the CDC report in 1991, in making their redhibition claim, plaintiffs are now claiming that they discovered their cause of action in 1993, when the Fourth Circuit affirmed the district court's finding that Orimune had been licensed in violation of federal regulations. Discovery of the existence of a defect, however, is not discovery of a legal theory upon which to base recovery for injuries sustained from the defect. Rather, a defect is "discovered" for purposes of the Louisiana statute when there is discovery of the facts which lead the buyer to conclude the product was defective. *See, e.g. White v. Ford Motor Co.*, 525 So.2d 96, 98 (La.Ct.App.1988); *Aegis Ins. Co. v. Delta Fire & Casualty Co.*, 99 So.2d 767, 782-85 (La.Ct.App.1957).

For the reasons stated above, the prescriptive period on the Kairdolfs' claims began to run in March 1987. Accordingly, plaintiffs' causes of action are barred.

CONCLUSION

Defendant Cyanamid's motion for summary judgment is granted. The Clerk of Court is directed to close the case.

SO ORDERED:

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT
UNITED STATES COURT HOUSE
40 FOLEY SQUARE
NEW YORK 10007

CAROLYN CLARK CAMPBELL
CLERK

At a stated term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse, Foley Square, in the City of New York, on the 6 day of November one thousand nine hundred and ninety-eight.

Stuart

plaintiff-appellant,

v Dkt No: 97-9548

American Home Produc

defendant-appellee.

A petition for rehearing containing a suggestion that the action be reheard in banc having been filed herein by the appellant Stuart.

Upon consideration by the panel that decided the

appeal, it is Ordered that said petition for rehearing is **DENIED.**

It is further noted that the suggestion for rehearing in banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

FOR THE COURT

CAROLYN CLARK CAMPBELL, Clerk

By: *Beth J. Meador*
Beth J. Meador,
Administrative Attorney

p o ccc
inbancdn__ frm

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER II--GENERAL POWERS AND DUTIES

Part F--Licensing of Biological Products and Clinical Laboratories

subpart 1--biological products

Sec. 262. Regulation of biological products

(a) Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales

No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from

place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.

* * *

(d) Regulations governing licenses; recall of product presenting imminent hazard; violations

(1) Licenses for the maintenance of establishments for

the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

(2)(A) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(B) Any violation of subparagraph (A) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this subparagraph shall, effective December 1 of each year beginning 1 year after the effective date of this subparagraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest \1/10\ of 1 percent. For purposes of this subparagraph, the term ``base quarter'', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter

is the arithmetical mean of such index for the 3 months comprising such quarter.

* * *

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRIAN KEITH STUART, a minor, by his natural guardian and next friend PAMELA JEAN CRAVEN, et al.	:
on behalf of themselves and all others similarly situated,	: 95 Civ. 4940 (AGS)
-against-	:
AMERICAN HOME PRODUCTS CORPORATION, and	:
AMERICAN CYANAMID COMPANY, a wholly owned subsidiary of AMERICAN HOME PRODUCTS CORPORATION,	:
Defendants.	:

STATE OF NEW YORK)
: ss.:
COUNTY OF ROCKLAND)

DAVID K. McCLINTOCK, being duly sworn, deposes and says:

1. I am Senior Director and Responsible Head, Regulatory Affairs and Technical Assessment, at the Lederle Laboratories Division of American Cyanamid

Company ("Cyanamid") and, as such, am fully familiar with the regulatory records maintained by Cyanamid. The information contained herein is based upon personal knowledge and/or my review of records maintained in the ordinary course of Cyanamid's business. I make this affidavit in support of Cyanamid's motion for summary judgment.

2. On March 27, 1962, the Department of Health, Education and Welfare, Division of Biologics Standards of the National Institutes of Health ("DBS") issued to Cyanamid's Lederle Laboratories Division a Product License to "propagate or manufacture and prepare for sale" live oral polio vaccine (OPV") Types 1, 2 and 3. The Product License specifically provides that "the requirements of the Public Health Service Act, approved July 1, 1994 (58 Stat. 682), for the regulation of biological products and of the regulations thereunder have been met with respect to the product(s) specified above." A true and correct copy of the Product License for OPV types 1, 2 and 3, as it is kept in the ordinary course of Cyanamid's business, is attached hereto as Exhibit A.

3. On June 25, 1963, DBS issued to Cyanamid's Lederle Laboratories Division a Product License to "Propagate or manufacture and prepare for sale" a trivalent OPV, DBS "having been satisfied that [applicable] requirements . . . have been met with respect to the product." A true and correct copy of the Product License for trivalent OPV, as it is kept in the ordinary course of Cyanamid's business, is attached hereto as Exhibit B.

4. Cyanamid has been producing and distributing its trivalent OPV under the trade name Orimune continuously since 1963. Since 1977, Cyanamid has been the sole source of this nations's OPV.

5. From approximately 1965 to 1983, Cyanamid produced its Type 3 Orimune lots from Seed 45B85, among others. After the FDA approved Seed 45B165 in August 1983, Cyanamid began to use that seed to produce its Type 3 lots of Orimune. Every seed that Cyanamid has used in the manufacture of Orimune was first officially approved for use, as complaint with applicable federal regulations, by the appropriate federal administrative agency, which at all times was either the DBS or a division of the Food and Drug Administration ("FDA").

6. Prior to distributing any particular lot of OPV to the medical community, Cyanamid was required by federal regulations to test the lot in the manner directed by the applicable federal regulations and to submit the test result data and samples of the lot to the DBS or FDA for analysis. Only if DBS and FDA determined that the particular lot was tested in accordance, and complied, with all applicable federal regulations would Cyanamid receive an official release from the DBS or FDA, certifying that the lot satisfied all applicable regulations and was permitted to be distributed. Cyanamid has received such a DBS or FDA release for each and every lot of Orimune that it has distributed and would not under any circumstances distribute a lot without receiving such a DBS or FDA release. True and correct copies of examples of such releases as they are kept in the ordinary course of Cyanamid's business are attached hereto as Exhibit C.

7. Like all pharmaceutical products, Orimune is accompanied by a package insert that describes, inter alia, the physical properties, biological functions, benefits and risks attendant to use of the vaccine. True and correct copies of two such package inserts as they are kept in the ordinary course of Cyanamid's business are attached hereto as Exhibit D.

David K. McClintock

David K. McClintock

Sworn to before me this
5th day of February 1996

Patricia Bocchino

Notary Public

Excerpts from American Cyanamid's Statement Pursuant to Southern District Local Rule 3(g) (statement of material facts as to which there is no general issue) Filed in Connection With Its Motion For Partial Summary Judgment

* * *

6. After undertaking its study, the Surgeon General's committee unanimously recommended that an OPV program be instituted in the United States. In re Sabin, 743 F. Supp. at 412-13.

7. After undertaking its study, the Surgeon General's committee also unanimously recommended that the OPV program use Dr. Sabin's Type 1, Type 2 and Type 3 OPV "strains." Id. at 413.

8. In March 1961, the Division of Biologic Standards ("DBS"), operating within the United States Department of Health, Education & Welfare's National Institutes of Health, adopted regulations governing OPV production, the issuance of manufacturing licenses and the approval and release of vaccine. Id.

9. In 1972, the DBS was transferred to the United States Food and Drug Administration ("the FDA") and was renamed the "Bureau of Biologics." Id. at 412 n.2.

Cyanamid's Orimune Program

10. In 1960, Cyanamid purchased Sabin strain material in order to create seeds and begin the manufacture of OPV. In re Sabin, 763 F. Supp. at 815.

11. By December of 1961, Cyanamid had conducted tests on its OPV product and submitted its test result data to the DBS in support of an application to manufacture the vaccine. Id.

12. In or about March 1962, the Surgeon General's ad hoc committee evaluated Cyanamid's application, determined that it met the regulatory requirements and recommended that the DBS grant Cyanamid a license to manufacture OPV. Id. at 816-17.

13. On March 27, 1962, the DBS issued to Cyanamid's Lederle Laboratories Division a Product License to "propagate or manufacture and prepare for sale" OPV Types 1, 2 and 3. Id.; Affidavit of David K. McClintock ("McClintock Aff.11), sworn to on February 5, 1996 and submitted herewith, ¶2, Ex. A.

14. Cyanamid's March 27, 1962 Product License specifically provides that, according to the Department of Health, Education and Welfare, "the requirements of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), for the regulation of biological products and of the regulations thereunder have been met with respect to the product(s) specified above." McClintock Aff., ¶2, Ex A.

15. A "trivalent" OPV is one that combines vaccine from "monovalent" Type 1, Type 2 and Type 3 lots. In re Sabin, 743 F. Supp. at 413 n.4.

16. On June 25, 1963, DBS issued to Cyanamid's Lederle Laboratories Division a Product License to "propagate or manufacture and prepare for sale" a trivalent OPV. McClintock Aff., ¶3, Ex. B.

17. Cyanamid's June 25, 1963 Product License provides that, according to the Department of Health, Education and Welfare, "the requirements of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), for the regulation of biological products and of the regulations thereunder have been met with respect to the product." McClintock Aff., 11 3, Ex. B.

18. Cyanamid has distributed an OPV product under the trade name Orimune(R) "Orimune") continuously since 1963. Id. at ¶4.

19. Since 1977, Cyanamid has been the sole supplier of OPV in the United States. Id.

20. Either the DBS or the FDA had approved for use, as compliant with applicable federal regulations, every OPV strain that Cyanamid has ever used in the manufacture of Orimune. Id. at ¶6.

21. Either the DBS or the FDA had approved for use, as compliant with applicable federal regulations, every OPV seed that Cyanamid has ever used in the manufacture of Orimune. Id.

22. From approximately 1965 to 1983, Cyanamid used Seed 45B85 (among other seeds) to produce its Type 3 Orimune lots. Id. at ¶5.

* * *

January 19, 1996

BY FACSIMILE AND
FIRST CLASS MAIL

Marc S. Moller, Esq.
Kreindler & Kreindler
100 Park Avenue
18th floor
New York, New York 10017

Re: Brian Keith Stuart, et al. v.
American Home Products Corporation. et uno.
95 Civ. 4940 (MGC)

Dear Mr. Moller:

In accordance with our telephone conversation last Friday, I am writing to convey to you in advance of our January 22 conference the grounds upon which we intend to move for summary judgment. As we discussed, we intend to move on strictly legal grounds, and will assume as true, for the purposes of our motion, all of the factual allegations of your complaint. Accordingly, there will be no need for you to conduct discovery in order to respond to the motion. Briefly stated below are the grounds for our anticipated motion.

First, we intend to assert that we are entitled to summary judgment dismissing the entire action based upon the statutes of limitations, repose and prescription applicable to the claims of each plaintiff. In particular, the sworn statements of the plaintiffs and the law in Nebraska and Louisiana lead inexorably to the conclusion that the claims of the Stuart plaintiffs expired no later than 1989 and the claims of the

Kairdolf plaintiffs expired no later than 1988. Thus, by the time this action was commenced in 1995, the claims of both plaintiffs had long been time-barred.

Second, we intend to argue that we are entitled to partial summary judgment on each claim to the extent it is based upon alleged "regulatory violations." This argument is based upon the indisputable facts that the Department of Biologic Standards and/or its successor agencies ("DBS") actually issued American Cyanamid a license to distribute oral polio vaccine and actually authorized the release of individual vaccine lots. While you may believe that the DBS should not have done so, your argument is one that the Court lacks subject matter jurisdiction to adjudicate because the DBS's decisions are administrative orders that cannot be collaterally attacked.

Third, we are entitled to summary judgment against any claim for punitive damages by these plaintiffs because the law of Nebraska and Louisiana each prohibits punitive damages.

As noted, because the grounds for our motion are strictly legal, we do not believe that there is any need at this time for depositions of current or former American Cyanamid officers or employees or for any other discovery from American Cyanamid. We will propose that no such discovery be permitted until after the disposition of the motion and will oppose any effort by you to conduct discovery in this case prior to such disposition.

Please call Monday morning if you wish to discuss the foregoing in advance of the 11:00 a.m. conference.

Sincerely,

Daniel J. Thomasch

Daniel J. Thomasch

cc: David Donovan, Esq. (via facsimile
and mail)

Stanley Kops, Esq. (via facsimile
and mail)

ALLEGATIONS FROM PLAINTIFFS' COMPLAINT

* * *

B. The Original Licensing of Defendant Lederle's Vaccine

35. Lederle was an early participant in the development of OPV. When the Surgeon General's Ad Hoc Committee recommended the Type I Sabin strain for use in the United States as a reference vaccine for neurovirulence testing, Lederle secured the Sabin strain material from which to derive its own seeds from Dr. Sabin via Merck (Sabin Original Merck -- "SOM") and manufacture its own vaccine. It tested its monovalent pools from the production seeds it developed from SOM in the summer of 1961 and submitted test results to the Division of Biological Services (DBS) in late December of that year.

36. Lederle did not submit data to the Surgeon General to establish that the "strain" of poliovirus they intended to use met the safety and potency requirements of 42 CFR §§ 73.110(b), 73.115 and 73.117, as required by § 73.110(b)(2)(i)[1].

37. Lederle obtained a product license for the manufacture and sale of its live oral poliovirus products based materials manufactured by Merck & Co. and designated SOM. SOM is one passage from SO, and SOM is, therefore, the first generation progeny of SO. SO is the SABIN ORIGINAL material.

38. In its trivalent product license application dated July 5, 1962, Lederle designated SOM as the master seed from which its product was derived.

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[1] Citations are to the regulations as originally promulgated.

39. SV40 (Simian Virus 40) was a known extraneous microbial agent in 1961 and 1962 when Lederle was submitting its original license applications for their OPV products.

40. No data were submitted by Lederle to the United States to demonstrate that the SOM material Lederle intended to use as master seed for the manufacture of "poliovirus vaccine, live, oral" was free of SV40 as required by 42 CFR § 73.110(b)(3). Lederle did not test SOM for SV-40 at the time of licensure.

C. Overview of neurovirulence testing

41. Lederle's vaccine had to comply with regulation- specified monkey neurovirulence test standards in order to qualify for licensure. 42 C.F.R. § 73.114(b)(1)(iii) provides, in part, that a "virus pool under test is satisfactory for poliovirus vaccine only . . . if a comparative analysis of the test results demonstrates that the neurovirulence of the test virus pool does not exceed that of the Reference Attenuated Poliovirus."

42. Monkey neurovirulence tests were conducted as follows. A given number of monkeys is inoculated with the material under test. Some of the monkeys are injected intrathalamically, i.e. at the stem of the brain, and others are injected intraspinally, i.e. at the base of the spine. Different groups of monkeys are injected with the tested material at different levels of dilution. (Levels of dilution range from 10^0 through 10^4 with 10^0 (undiluted) being the most concentrated level). After the monkeys have been inoculated, they are kept under observation for at least 17 to 21 days. At the end of the observation period, they are sacrificed and a pathological examination is performed on sections of histologic material taken from their brains, their spinal cords and their lumbar spines.

43. The results of the tests are then recorded and the data arrayed so that a comparative analysis can be made. The regulations require that five factors be taken into account in this analysis: "(a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those

characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma." 42 C.F.R. § 73.114(b)(1)(iii).

44. Dr. Ruth Kirschstein, the DBS[2] official in charge of evaluating neurovirulence data in the 1960s and early 1970s, and all the other individuals responsible for the said tests, including the Government employees as well as the employees of Lederle devised a grading system for comparing test results. Under this system, the sections of histologic material taken from a monkey were assigned a number, ranging from "0," indicating no polio lesions, to "4," reflecting severe polio lesions. If the section being tested was at the site of the inoculation, the number assigned to it was referred to as the "severity score." If, on the other hand, the section being tested was the one most distant from the site of the inoculation, it was referred to as the "spread score." Thus, in an intrathalamic test the section of histologic material taken from the brain would provide a severity score and the section of material taken from the lumbar spine area would provide the spread score.

45. Lederle did not submit data to any agency of the United States to demonstrate that the SOM material used as master seed for each type of polio vaccine which it intended to use to manufacture "production seeds" had demonstrated neurovirulence in Macaca monkeys no greater than that of the NIH Reference Attenuated Poliovirus, in accordance with § 73.110(b)(4). Lederle did not test SOM for neurovirulence at the time of licensure.

46. Lederle in its July 5, 1962 application for a product license for its trivalent live oral polio vaccine stated that it tested its master seeds intramuscularly, intrathalamically and intraspinally, but no data were submitted by Lederle to substantiate this claim, as no tests were,

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[2] DBS is the name given to the United States of America's Agency which initially approved the license of defendant. It stands for the Division of Biologic Standards which at that time was part of the National Institute of Health.

in fact, conducted and compared to the N.I.H. Reference Attenuated Poliovirus Vaccine.

47. Lederle utilized SOM Type I and Seed 1102 to produce the monovalent pools for lots 113, 114, 115, 116 and 117 for both the trivalent and monovalent license.

48. Lot 116 was derived from SOM Type I and lots 113, 114, 115 and 117 were derived from Production Seed 1102.

49. Sabin Seed P712 Ch. 2ab (SOM) was utilized to produce Type II Monovalent Pool Number 213.

50. Lederle Seed Number 2107 (sometimes referred to by Lederle as 2017) was utilized to produce Type II monovalent pool numbers 214, 215, 216 and 217.

51. The first five licensing lots of Type II Poliovirus manufactured by Lederle were monovalent pool numbers 213, 214, 215, 216 and 217.

52. Sabin Seed Leon-12 a_1b (SOM) was utilized by Lederle to make Lederle Seed Numbers 3101, 3102, 3107, 45B-73 and 45B-75, Type III.

53. Lederle Seed Numbers 3102 and 3017 were utilized to produce Type III Monovalent Pool Number 314, and Lederle Seed Number 3102 was utilized to produce Type III Monovalent Pool Numbers 313, 315, 316 and 317.

54. The first five licensing lots of Type III Poliovirus manufactured by defendant were Monovalent Pool Numbers 313, 314, 315, 316 and 317.

55. Prior to the issuance of a product license by the United States, Lederle did not submit to the United States data demonstrating that Lederle's Production Seed and SOM for Type I,

Type II and Type III poliovirus vaccine, live, oral was free of extraneous microbial agents as required by § 73.110(b)(3).

56. Prior to the issuance of a product license for Type I, Type II and Type III poliovirus vaccine, live, oral, Lederle did not submit to the United States monkey neurovirulence test results on all SOM Type I, II or III and/or the production seeds derived therefrom.

57. In order to obtain a license for its Type I, Type II and Type III Vaccine, Lederle had to demonstrate, inter alia, that the results of the monkey neurovirulence tests which it performed on its licensing lots of Type I, Type II and Type III Vaccine did not exceed the results of similar tests which it performed on the Type I reference standard (commonly referred to as NA-2 and thereafter, NA-3, NA-4, etc.). As an additional safety assurance, DBS required that this demonstration be made as to five consecutive lots manufactured under the same conditions and derived from the same virus seed (production seed).

58. Prior to the issuance of a product license for its Type III OPV, Lederle did not submit to the United States monkey neurovirulence test results on Production Seed 3102 as required by § 73.110(b)(4) by comparison with the N.I.H. Reference Attenuated Poliovirus, which results would have showed whether the vaccine met the safety regulations.

59. Prior to the issuance of a production license for Type III poliovirus vaccine, live, oral, Lederle did not submit to the United States intrathalamic or monkey neurovirulence test results pertaining to Production Seed 3107 as required by § 73.110(b)(4) by comparison with the N.I.H. Reference Attenuated Poliovirus, which results would have showed whether the vaccine met the safety regulations.

60. Prior to the issuance of a product license for Type III Poliovirus Vaccine, live, oral, the protocols submitted by Lederle to the United States as part of its application for a product license did not contain a comparative evaluation of the monkey neurovirulence

tests for lots 313, 314, 315, 316 and 317 with the NIH Reference Attenuated Polio Virus as required by
§ 73.114(b)(1)(iii), which results would have showed whether the vaccine met the safety regulations.

61. Lederle never had as a final grade on the NIH Reference Attenuated Poliovirus, NA-2, NA-3 or NA-4 on the intrathalamic monkey neurovirulence test performed by Lederle between 1961 and 1983 a "severity" score of 3 or higher or a "spread" score of 3 or higher.

62. In the Protocol submitted by Lederle to the United States of America for monovalent lot 314 as part of its Type III polio license application, one monkey showed a grade 3 "severity" score and exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intrathalamic portion of that test.

63. In the Protocol submitted by Lederle to the United States of America as part of its Type III polio monovalent lot 315 license application, one monkey showed a grade 3 "severity" score and a grade 3 "spread" score, and this exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intrathalamic portion of the test.

64. In the Protocol submitted by Lederle to the United States of America for monovalent lot 317 as part of its Type III polio license application, two tests were submitted. On one test, one monkey had a grade 4 "severity" score and on a second test, two monkeys showed grade 3 "severity" scores and one monkey had a grade 3 "spread" score. This exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intrathalamic portion of the test.

65. Lederle's intrathalamic monkey neurovirulence tests of lots 314, 315, and 317 submitted to the United States to support its license application for a Type III product license showed monkey virulence scores in excess of the NIH Reference Attenuated Poliovirus, NA-2 in the intrathalamic portion of the test.

66. Section 73.116(c) of the regulations provides that "no lot of vaccine shall be released unless each monovalent pool contained therein is one of a series of five consecutive pools of the same type, each pool having been manufactured by the same procedures and each having met the criteria of neurovirulence for monkeys prescribed in § 73.114(b)(1), and of the in vitro markers as described in § 73.114(b)(3).

67. Section 73.116(c) precluded a product license for Lederle for Type III OPV based upon the intrathalamic monkey neurovirulence scores of Lederle pertaining to monovalent lots 314, 315 and 317, each of which exceeded the NIH Reference Attenuated Poliovirus NA-2 on the intrathalamic portion of the test.

68. Lederle used lots 313, 314, 315, 316 and 317 for its clinical field trials of Type III Poliovirus Vaccine, live, oral, in violation of § 73.117, for both its monovalent and trivalent license applications.

69. In the entire history of monkey neurovirulence testing of NIH Reference Attenuated Poliovirus, NA-2, NA-3 or NA-4 by Lederle from 1961 to 1983, Lederle never recorded a final monkey neurovirulence score on the same monkey both grade 3 for "severity" and a grade 3 for "spread" on the intraspinal test.

70. In the Protocol submitted by Lederle to the United States of America for monovalent lot 313 as part of its license, one monkey had a final grade 3 as to "severity" and a final grade 3 as to "spread", and this exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intraspinal portion of the test.

71. In the Protocol submitted by Lederle to the United States of America for monovalent lot 314 as part of its license, one monkey had a final grade 3 as to "severity" and a final grade 3 as to "spread" and this exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intraspinal portion of the test.

72. In the Protocol submitted by Lederle to the United States of America for monovalent lot 315 as part of its license, one monkey

had a final grade 3 as to "severity" and a final grade 4 as to "spread", and this exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intraspinal portion of the test.

73. In the Protocol submitted by Lederle to the United States of America for monovalent lot 316 as part of its license, one monkey had a final grade 3 as to "severity" and a final grade 3 as to "spread", and this exceeded the NIH Reference Attenuated Poliovirus, NA-2 on the intraspinal portion of the test.

74. Based upon Lederle's intraspinal monkey neurovirulence test scores submitted as part of its license update for Type III Poliovirus Vaccine, live, oral, four out of the five monovalent pools exceeded the NIH Reference Attenuated Polio Virus, NA-2 on the intraspinal portion of the test.

75. Lederle violated § 73.114(b) (1) (i) (ii) (iii) in receiving a product license for Lederle's Type III OPV based upon the monkey neurovirulence findings submitted by Lederle with respect to Lots 313, 314, 315, 316 and 317.

76. Lederle violated § 73.114(b) (1) (i) (ii) (iii) in receiving a product license for Lederle's Type I OPV based upon the monkey neurovirulence findings submitted by Lederle with respect to Lots 113, 114, 115, 116 and 117.

D. Neurovirulence Testing from 1962 to 1973

77. Lederle did not manufacture five monovalent pools of Type III vaccine which met the safety standards of the Reference throughout the licensing period. This led to numerous cases of paralytic poliomyelitis from the vaccine shortly after licensure of the Lederle product.

78. Thereafter, in order for Lederle to meet the safety requirements, it applied, with the knowledge of DBS officials, a statistical model which did not comply with the federal regulatory standards known as the "Maloney Table" for the purpose of

conducting comparative analysis of neurovirulence test results. The Maloney Table only utilized intrathalamic results; the intraspinal results were not utilized to either pass or fail a monovalent pool, even though the test was conducted. The effect was that that table, which was derived in part from Type III data, was substituted for the actual results of the tests on the reference vaccine, as required by the Code of Federal Regulations. The table, unlike the reference history data, permitted a grade 4 monkey or a grade 3 monkey and liberalized the release criteria. It further allowed increasing the number of monkeys tested in order to get a monovalent pool passed which would otherwise have failed on its first test. It allowed up to at least 20 re-tests.

79. The Maloney Table did not utilize the intraspinal test results. According to Lederle documents authored in September 1977 by Dr. Ronald Vallancourt, the "Responsible Head" of Lederle, Lederle did perform the intraspinal tests but, in violation of regulations, did not use the results of those tests to pass or fail individual monovalent pools. Dr. Albert Sabin and other experts, prior to the enactment of the regulations, stressed the importance and the need for the intraspinal test and considered that test crucial as part of the evaluation of the safety of the vaccine. As of 1977, the only test upon which the vaccine was released was the intraspinal test results in most of the world. As of 1991, the United States regulations relied solely upon the intraspinal test results.

80. In 1972, DBS was reorganized and transferred from the National Institutes of Health to the Food & Drug Administration. The agency's responsibilities and functions remained the same. DBS was re-named the Bureau of Biologics, hereinafter referred to as BOB.[3]

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[3] The name of this Government Agency has changed several times from 1972 to the present. Its current name is the Center for Biological Evaluation.

81. During the period from 1962 through at least 1977, Lederle did not use the intraspinal test to pass or fail monovalent pools.

82. During the period from 1962 through at least 1977, in order to comply even with the statistical model, known as the Maloney table, on occasion it was necessary to combine the Lederle test and the Government's test in order for the monovalent pool to qualify for release on the intrathalamic test, which is contrary to the regulations, and contrary to good scientific practice.

83. On the intrathalamic tests conducted by DBS/BOB[4] on monovalent pool 450, there was a monkey with a severity score of 3 and a spread score of 3. There had never been a 3/3 monkey in DBS's tests of the Reference. Nevertheless, monovalent pool 450 would have passed under the traditional "final neurovirulence grade" method of analysis because the 3/3 monkeys which appeared would have been assigned a final neurovirulence grade of 3, which had been seen on the Reference on the Government's test. To fully comply with the safety regulations, a dual severity/spread scoring system would have resulted in the rejection of that monovalent pool.

84. Because the government determined to enforce its regulations as written at least in regards to intrathalamic tests, this raised serious concerns at Lederle and led to a series of meetings between Lederle and DBS personnel. At the first such meeting, on September 13, 1977, DBS advised Lederle of the proposed failure of two monovalent pools, a Type I Pool, 217, and a Type III monovalent Pool, 450, under the dual severity/ spread scoring method. Lederle noted that if the monovalent pools were rejected, Lederle would require at least twelve months to reestablish consistency under 42 C.F.R. § 73.116(c). Lederle claimed that this would raise a severe supply problem.

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[4] For the purposes of this Complaint, DBS and BOB are interchangeable terms, but in order to be consistent, plaintiff will utilize the original name of the said Government Agency.

85. Dr. Ronald J. Vallancourt, manager of Lederle's Biological Section, "left the [September 14, 1977] meeting with a distinct impression that Dr. Meyer [Harry M. Meyer, Jr., the Director of DBS] will strongly consider a change in the regulations to allow for the rejection of a monovalent pool without the resulting break in consecutiveness."

86. In the wake of the September 13, 1977 meeting, Lederle officials understood that its failure to follow the dual scoring system was in violation of the federal regulations governing OPV neurovirulence testing. On September 22, 1977, Dr. Vallancourt met with Dr. Elisberg and reviewed all of DBS's testing records. Dr. Vallancourt after reviewing the data concluded that if the intraspinal test and intrathalamic test were applied as the regulations required to all the lots produced from Seed 45B85 (the Seed Lederle had been using since approximately 1964), fifty-three percent of all the monovalent pools exceeded the Reference Standard on at least one test and should have been rejected.

87. Lederle was further advised that as to its original licensing monovalent pools of Type III, a retrospective analysis indicated that all of those monovalent pools failed the appropriate safety tests and should have all been rejected. It had already known no later than August 1963 that at least three monovalent pools of its licensing lots failed using even the statistical Maloney Tables.

88. Lederle officials knew that the continued use of the dual scoring system presented a crisis for Lederle in that its OPV product failed federal neurovirulence standards prescribed by the applicable regulations. One of its internal memoranda warned that if that scoring system were adopted, "it could have very grave consequences." This was especially true as regards the intraspinal test which Lederle did not use to pass or fail a monovalent pool.

89. On October 19, 1977, Dr. Vallancourt and Mr. D. Carroll (who was on the business side at Lederle and subsequently became its president) again met with DBS officials. Mr. Carroll began the meeting by noting that the "sudden change in interpretation of polio,"

i.e., the shift to a dual scoring system, would "cause Lederle to be out of business--since [DBS] would say 50% would fail using new criteria." He stated, according to notes taken by Dr. Parkman, that Lederle would be unwilling to invest its resources to reestablish consistency "if method of evaluation was to be changed so that 50% would fail."

90. The problem grew worse in November of 1977 when problems arose with monovalent pool 451 of Type III. In a telephone conversation, Dr. Vallancourt informed Drs. Meyer, Parkman and Elisberg that delays in reestablishing consistency "could cause supply & inventory problems."

91. A final meeting was held December 21, 1977. According to a Lederle memorandum, all the participants agreed "that [Lederle's] Type III is more neurovirulent than Type I Reference." The memorandum further stated: "Dr. Meyer asked us to bear with them in their efforts to change regulations which may be accomplished in mid 1978. In interim we are advised to release our protocols as we have been i.e.: avoid critical review of intra-spinal results; consider grade 3 lesion on Type III test as acceptable on intra-thalamic test. Where we have a question Dr. Ubertini will call Dr. Elisberg before signing and releasing a neurovirulence protocol. Dr. Meyer stated that during this period [DBS] and Lederle must continue with guidelines that may be technically outside the regulations as written but we must do this if we are to continue to offer vaccine."

* * *

SECOND CLAIM FOR RELIEF -
FRAUD AND MISREPRESENTATION

111. Plaintiffs incorporate by reference all of the foregoing allegations as if fully set forth herein.

112. Defendants intentionally misrepresented and falsely warranted in writing to health care professionals throughout the United States, including the medical providers of the plaintiff-vaccinees and the medical providers of the contacts of the un-vaccinated class member polio victims, as well as to plaintiffs, that Orimune was licensed, manufactured, tested and released into commerce in accordance with the regulations as promulgated by the FDA concerning live polio virus vaccine.

113. As part of its scheme and artifice to defraud, defendants intentionally failed to disclose that its officers and employees knew that the Type III component in the Orimune product was excessively neurovirulent and did not meet federal safety regulations.

114. The parents of certain of the infant vaccine recipients were required to sign a statement which set forth that a certain risk -- approximately 1 in several million -- existed that an Orimune vaccinee could contract actual paralytic polio. The representation of the particular risk communicated to signatories of the acknowledgment, including plaintiff PAMELA JEAN CRAVEN on March 19, 1979 with respect to the vaccination of BRIAN KEITH STUART, was based upon an oral polio vaccine which satisfied all government safety regulations, and not upon the vaccine that defendants were actually making available to health care professionals, such as the University of Nebraska Medical Center in the case of PAMELA JEAN CRAVEN. Further, such statistical information was inaccurate, and defendants knew it.

115. As part of its scheme and artifice to defraud, defendants intentionally failed to disclose that their officers and employees knew that prior to the administration of Orimune to plaintiff vaccinees or the contacts of the un-vaccinated class member polio victims, their representations concerning the degree of risk to a member of the general public of contracting polio as a result of ingestion of Orimune or contact with an Orimune vaccinee was false and misleading.

116. As part of their scheme and artifice to defraud, defendants

intentionally failed to disclose that their officers and employees knew prior to the dates of vaccinations of vaccinees or their contacts that at least 53% or more of the Type III poliovirus component in Orimune failed to meet the Federal safety standards, including 42 C.F.R. § 73.114 and that vaccine released after the meetings of 1977 were excessively neurovirulent.

117. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that their representations of compliance with federal safety regulations, though knowingly false, were made to induce medical care providers to continue to use Orimune rather than an alternative poliovirus vaccine and to induce reliance on those representations by medical care providers and members of the public.

118. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that they made false representations about regulatory compliance to frustrate litigation by victims who might contract vaccine-associated polio, and furthermore to create an opportunity for misleading defenses to be raised in litigation.

119. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that their officers and employees knew that the Type III component in the Orimune product made available to the American health care community at and around the time plaintiffs or their contacts were immunized and the class member polio victims experienced their initial paralytic symptoms was more neurovirulent than the regulations permitted.

120. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that their officers and employees knew that their original licensing was improper and contrary to the federal regulations.

121. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that their officers and employees knew that there were discrepancies between OPV which was actually manufactured and marketed and OPV which was permitted by regulation to be manufactured and marketed, and that those

differences could, in fact, be linked to the Type III component of the vaccine that defendants released for utilization in the United States, which failed to comply with the Government's promulgated regulations and was in use at and around the time plaintiff vaccinees or their contacts were immunized and class member polio victims thereafter experienced their initial paralytic symptoms.

122. As part of their scheme and artifice to defraud, defendants intentionally failed to disclose that their officers and employees knew that a series of meetings had taken place between September and December of 1977 which discussed results of various tests performed on the Lederle Type III component. Those test results indicated that Lederle had not complied with the Code of Federal Regulations, as promulgated.

123. As part of their scheme and artifice to defraud, defendants knew that the statistical risks utilized in and communicated through its package insert did not include all the possible cases of vaccine-associated polio, and that a misleading statistical formula was being used which diminished the actual risk to the susceptible population. A more accurate representation of risk of the vaccine's danger on the first dose was less than 1 in 500,000 to the child and his or her contacts.

124. As part of their scheme and artifice to defraud, defendants knew that their vaccine manufactured from the Pfizer material which they produced was beyond the five permitted tissue culture passages and could not be released and be in compliance with 42 C.F.R. § 73.113(b).

125. Plaintiffs, as well as virtually all medical professionals who administered Orimune and/or treated persons who had received Orimune as a regular part of their practice and duties, were unaware at all times relevant hereto of the falsity of the aforementioned representations and warranties made by defendants concerning Orimune.

126. Plaintiffs reasonably relied on the aforementioned false and fraudulent representations of defendants concerning Orimune, and further relied upon defendants to market solely and exclusively a polio vaccine which conformed fully to applicable federal safety and licensing requirements, causing them to be damaged.

127. As a result of defendants' aforesaid acts and omissions involving fraud and misrepresentation, with resulting injury and damages to the class members, plaintiffs suffered the injuries and damages as set forth herein and are entitled to both compensatory and punitive damages from defendants.

* * *

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER XIX--VACCINES

Part 2--National Vaccine Injury Compensation Program

subpart b--additional remedies

Sec. 300aa-23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a
vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title

shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in--

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.